



Electronic Request for Proposal

SECTION A – SOLICITATION/CONTRACT FORM

OFFERORS ARE RESPONSIBLE FOR ROUTINELY CHECKING THE CMB WEBSITE <http://www.niaid.nih.gov/contract/default.htm> FOR ANY POSSIBLE SOLICITATION AMENDMENTS THAT MAY BE ISSUED. NO ADDITIONAL NOTIFICATION OF ANY AMENDMENTS WILL BE PROVIDED BY THIS OFFICE.

Purchase Authority: Public Law 92-218, as amended. NOTE: The issuance of this solicitation does not commit the government to an award.			
RFP Number: NIH-NIAID-DAIDS-03-13	Just In Time: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Small Bus. Set-Aside <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No 8(a) Set-Aside <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No NAICS Code: 54171 Size Standard: 500 employees	Level of Effort: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Total Effort: []
TITLE: HLA Typing and Epitope Mapping Relative to HIV Vaccine Design			
Issue Date: May 30, 2002	Due Date: September 16, 2002 Time: 4:00 PM, EST	Technical Proposal Page Limits: <input checked="" type="checkbox"/> Yes (see "How to Prepare and Submit Electronic Proposals") <input type="checkbox"/> No	
ISSUED BY: Paul D. McFarlane, Contracting Officer Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive Room 2230, MSC 7612 Bethesda, MD 20892-7612		<input checked="" type="checkbox"/> <i>We reserve the right to make awards without discussion.</i>	
NO. OF AWARDS: <input checked="" type="checkbox"/> Only 1 Award <input type="checkbox"/> Multiple Awards		PERIOD OF PERFORMANCE: Five (5) years beginning on or about 05/08/2003	
Offers will be valid for 120 days unless a different period is specified by the Offeror on the form entitled "Proposal Summary and Data Record, NIH-2043" (See SECTION J - Attachments)			
The Official Point of Receipt for the purpose of determining timely delivery is the Contract Management Branch as stated above. The paper copy with original signatures is the official copy for recording timely receipt. If the paper copy of your proposal is not received by the Contracting Officer or Designee at the place and time specified, then it will be considered late and handled in accordance with HHSAR 352.215-70 entitled "Late Proposals and Revisions" located in this Solicitation. FACSIMILE SUBMISSION OF PROPOSALS IS NOT ACCEPTABLE.			
POINT OF CONTACT -- Scott Drega --COLLECT CALLS WILL NOT BE ACCEPTED--			
Telephone: Direct 301-496-6424 Main 301-496-0612		Fax 301-480-5253	E-Mail SDrega@niaid.nih.gov

TABLE OF CONTENTS

SECTION A -- SOLICITATION/CONTRACT FORM COVER PAGE

BACKGROUND

STATEMENT OF WORK (with attachments)

NOTES TO OFFERORS

REPORTING REQUIREMENTS and OTHER DELIVERABLES

SECTIONS B – H -- [UNIFORM CONTRACT FORMAT - GENERAL](#)

SECTION I -- GENERAL CLAUSES and ADDITIONAL CLAUSES / SUBSTITUTED CLAUSES

SECTION J -- LIST OF ATTACHMENTS

**SECTION K -- REPRESENTATIONS AND CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS OR
QUOTERS (NEGOTIATED)**

SECTION L -- INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

- 1. General Information**
- 2. Instructions to Offerors**
 - a. General Instructions**
 - b. Technical Proposal Instructions**
 - c. Business Proposal Instructions**

SECTION M -- EVALUATION FACTORS FOR AWARD

BACKGROUND / STATEMENT OF WORK / NOTES TO OFFERORS

Background

HLA Typing and Epitope Mapping Relative to HIV Vaccine Design DAID-03-13

The National Institute of Allergy and Infectious Diseases (NIAID) supports a comprehensive portfolio of grant and contract resources to discover, develop and test potential vaccines to prevent and treat infections caused by Human Immunodeficiency Virus-1 (HIV-1).

Increasing evidence indicates that the host immune response plays a critical role in defining the viral set-point and clinical disease progression in persons infected with HIV-1, and that vaccine-elicited cellular immune responses can successfully attenuate infection and mitigate disease progression in a monkey model. The ability of neutralizing antibodies to offer sterile protection against challenge with HIV-1 has been also clearly demonstrated by passive immunization studies. An emerging consensus is that an effective HIV-1 vaccine should induce potent virus-specific cytotoxic T lymphocyte responses (CTL) and neutralizing antibodies, and thus, understanding of the viral targets of these responses is paramount to the design and testing of candidate vaccines.

The greatest need for an HIV-1 vaccine resides among populations in resource-poor settings. Ninety percent of new infections occurs among non-Caucasian populations infected with non-clade B viruses. Little is known about the range and diversity of the genetic and ethnic backgrounds in these infected populations and a scientific knowledge gap exists as to how genetics and ethnicity affect immune responses to HIV-1. Most of the current generations of HIV vaccines are based on the induction of memory CTLs. Much information exists about the process by which CTL lyse virus-infected cells. The specific lytic process involves the interaction of the host HLA molecules with peptide sequences, or “epitopes”, present in the virus. In that regard, selecting an HIV vaccine strain best suited for a particular population may need to take into account the predominant HLA type(s) and the circulating virus subtype(s) in that population. In addition, HIV is a highly variable virus, and the peptide sequences that identify CTL and helper epitopes may differ among virus strains and subtypes. Therefore, the viral epitopes that would trigger a protective response may differ depending on the HLA type of the individual and the genetic subtype of the infecting virus.

The purpose of this contract is to support acquisition of specific datasets by studying the immune responses of individuals infected with non-clade B HIV-1 at one or more international location(s). These datasets include: a) DNA-based molecular HLA class I and II typing of selected HIV seropositive and seronegative populations at existing or proposed international vaccine trial sites; b) characterization of cellular immune responses and the mapping of CTL epitopes and helper epitopes that are restricted by common HLA types; c) measurement of neutralizing antibody responses; d) identification, characterization and sequencing of circulating HIV-clade variants; and e) establishment of a database of HLA-types, associated T cell epitopes, antibody responses, and viral variants.

The “HLA Typing and Epitope Mapping to Guide Vaccine Design” initiative was first competed in 2000. This competition attracted a high level of interest and quality of Offerors. One award, N01-AI-15442, with Massachusetts General Hospital was instituted in May 2001. The emphasis in N01-AI-15442 is measuring HIV-specific T cell immune responses and performing viral sequencing in HIV-1 clade B-infected non-Caucasian populations in the Americas, and in non clade-B infected populations in South Africa. The purpose of this initiative is to expand acquisition of the datasets described above into additional, new, international sites.

Statement of Work
HLA Typing and Epitope Mapping Relative to HIV Vaccine Design
RFP DAID-03-13

Independently, and not as an agent of the Government, the Contractor shall furnish all necessary services, qualified personnel, materials, equipment, and facilities needed to perform the work described below.

- 1) Establish a research and administrative team that includes all expertise needed to: select and acquire HIV+ and HIV- human specimens; perform DNA-based molecular HLA class I and II typing in selected seropositive and seronegative populations; perform an array of immunologic assays, in particular CD8+ and CD4+ T lymphocyte cellular assays; identify CTL and immunodominant T helper epitopes and their respective HLA-restricting elements in HIV-infected individuals; measure neutralizing antibody responses in HIV-infected people; perform sequence analysis of the HIV viral variants in the geographic location(s) of the cohorts to be vaccinated; and establish a database of the acquired immunogenetic, immunologic and virologic information. Table 1 (pages A-9-10) summarizes the Government expectations of the Offeror. **(See Note to Offeror # 1-3)**
- 2) Select, secure, receive, catalog, process and store samples from uninfected and HIV-infected individuals at international sites that are very likely to conduct future HIV-1 vaccine trials. Sampling may include: whole blood, viably cryopreserved blood mononuclear cells, serum, other tissues or body fluids, and virus culture supernatants from. The Contractor shall arrange for samples to be shipped from the supplier directly to the Contractor or to a central sample processing facility. The handling and transportation of all samples under this contract shall be in accordance with all applicable local, state, Federal and international regulations including health and safety standards. All samples received by the Contractor shall be accompanied by a data report form (DRF) containing epidemiological information that will include the subject's age, sex, risk factors, approximate date of infection, and other medical history deemed pertinent by the Project Officer. No personal identifiers will be included. Data capture forms used for this purpose shall be developed by the Contractor and are subject to approval by the Project Officer. **(See Note to Offeror # 4-5)**

The Contractor shall:

- a) Develop a plan, subject to modification by the Project Officer, to select and acquire samples from international site(s). The Project Officer reserves the right to request that the Contractor analyze specimens from an international site that the Contractor may not have proposed, but that may be important to future NIAID-sponsored vaccine trials. The Contractor or SubContractor will be required to utilize these samples to perform an array of molecular HLA-typing, immunologic and virologic assays that are specified in [3-7] below.
- b) Define and ensure adherence to laboratory safety guidelines, and if necessary train investigators in the most suitable manner for processing, freezing and shipping of cells, plasma and serum samples using standard operating procedures (SOPs) and assist, when necessary, in arranging for the transfer of virus-infected samples from designated sites to the Contractor site or central sample processing facility. All shipments shall be coordinated so that viability of the samples is not adversely affected and shall adhere to all safety regulations.
- c) If necessary, ship containers to sites providing frozen samples. The shipping containers must provide a sufficient margin of safety for maintaining appropriate environmental safeguards and desired refrigeration levels for specific products in transit, depending on the mode of transportation.
- d) Obtain the appropriate licenses and permits required by local, state, and Federal authorities for the safe import, handling, storage and distribution of biohazardous samples.
- e) Obtain documentation from the sample supplier to ensure specimen acquisition in accordance with federal requirements for the protection of human subjects from research risk.
- f) Develop, track, code and maintain an inventory of participant specimens collected under this contract, for example, condition and volume of sample, temperature maintained in transit, method of processing, storage conditions, specific storage location. The Database Management System (DBMS) used shall be relational. It shall be able to receive and electronically transfer data from/to EXCEL spreadsheets.
- g) Transfer to the computer-based inventory and distribution database, and compile, all data from epidemiological data capture forms that accompany each sample.

- 3) Determine HLA class I (A, B and C) and class II (DR, DQ, DP) genotypes in the samples received and determine their allelic distribution.
(See Note to Offeror # 6-7)
 - a) Extract DNA from blood or tissue samples from HIV-infected and control samples.
 - b) Perform HLA Class I typing by the technique of low resolution DNA molecular analysis on all samples.
 - c) Perform HLA Class II typing by the technique of low resolution DNA molecular analysis on all samples.
 - d) Based on the evaluation in (b), and in conjunction with the Project Officer, identify an appropriate subset of samples for further examination by high-resolution molecular DNA HLA class I typing.
 - e) Evaluate the data to determine if there is an association between one or more allele groups and a particular immunological/clinical event or outcome.
- 4) Measure CTL responses and assess the specificity of the intra and inter-subtype cross-reactivity. To ensure comparability of results with other DAIDS-sponsored studies, the Offeror shall employ common key reagents, such as recombinant vaccinia viruses expressing HIV gene products, and peptides from the AIDS Research and Reference Repository. **(See Note to Offeror # 8)**

The Offeror should:

- a) Generate EBV-transformed B lymphoblastoid cell line (BLCL) to serve as target cells in the CTL killing assays.
 - b) Perform bulk culture HIV specific CTL analyses after polyclonal stimulation and with multi-gene HIV clade specific antigens, expressed from recombinant pox virus or with peptide pools.
 - c) Perform CTL killing assays using a panel of clade specific recombinant vaccinia viruses expressing HIV gene products such as envelope, gag, pol and nef as the source of antigen. The Contractor is responsible for selecting and obtaining the appropriate vaccinia constructs expressing HIV-1 genes for performing the assays.
 - d) Determine CTL cross clade killing reactivity at a polyclonal level.
- 5) Determine cellular immune responses using state-of-the-art technologies, for example, ELISPOT, intracellular cytokine staining, or tetramer staining, and assess the specificity of the CD8+ responses (intra and inter-subtype cross-reactivity). To ensure comparability of results with other DAIDS-sponsored studies, the Offeror shall employ common key reagents, such as peptides from the AIDS Research and Reference Repository. **(See Note to Offeror # 9)**
 - a) For ELISPOT assays: perform PBMC and CD8+ T cell analyses after stimulation with multi-gene HIV clade specific peptide pools.
 - b) Determine ELISPOT cross clade reactivity at a polyclonal level.
 - c) Develop a plan to validate ELISPOT or other cellular immune assays by cross-testing of cells from established DAIDS clinical trial networks.
 - d) Perform additional cellular immune assays as they become available for large-scale use or as specified by the Project Officer.
- 6) Map CTL epitopes restricted by HLA types. **(See Note to Offeror # 10)**
 - a) Determine MHC restriction of CTL responses.
 - b) Map CTL epitopes restricted by common HLA types to identify epitope rich regions and/or immunodominant CTL epitopes.
 - c) Identify CTL epitopes that are restricted preferentially by a single HLA allele.

- d) Fine map novel epitopes utilizing peptides in ELISPOT or similar assays.
- e) Determine CTL cross clade reactivity of specific epitopes at a clonal level.
- 7) Measure and map CD4 T helper cell responses. **(See Note to Offeror # 11)**
 - a) Perform assays for T helper cell function, e.g. antigen-induced proliferation, ELISPOT on CD4+ T cells.
 - b) Identify immunodominant T helper epitopes in HIV Envelope and Gag.
 - c) Fine map epitopes utilizing peptides in ELISPOT assays
- 8) Characterize neutralizing antibody responses of viral isolates. **(See Note to Offeror # 12-13)**
 - a) Develop an algorithm to guide the performance of neutralizing antibody assays, such as testing against laboratory adapted circulating strains of virus, followed by clade specific primary isolates, followed by primary isolates from multiple clades.
 - b) Perform neutralization analysis of virus isolates obtained in #9 below, as well as of selected viral isolates used by the HVTN Central Laboratory, and obtainable by consultation with the Project Officer. The neutralization assays should be adaptable to performance in primary peripheral blood leukocytes, genetically manipulated cell lines, established cell lines or other systems, as approved in advance by the Project Officer. The reagents to be used shall include autologous and heterologous human sera as well as additional monoclonal and polyclonal antisera to be provided by the Project Officer.
 - c) Perform other assays, as they become available for large-scale use, to measure virus neutralization as specified by the Project Officer, including but not limited to: flow-cytometric assays, antibody-dependent cytotoxicity assays, gp120/CD4 blocking assays.
- 9) Perform HIV viral load measurements, isolation, expansion and characterization of samples supplied to the Contractor **(See Note to Offeror # 14-15)**
 - a) Perform assays to quantitatively determine the level of HIV in plasma of infected humans. Assays to be conducted may include, but are not limited to bDNA, NASBA, or PCR assays. The contractor shall demonstrate the level of sensitivity and reproducibility of the selected assay, including the level of signal obtained with virus-negative samples from uninfected humans. The contractor shall also include appropriate positive and negative controls with each set of samples assayed to provide quality control and ensure consistency of the assay.
 - b) Isolate HIV-1 or related lentiviruses from acquired samples of human PBMC co-cultures or other state-of-the-art culture procedures, as approved, in conjunction with the Project Officer.
 - c) Monitor virus growth by HIV-1 p24 antigen capture analysis or other methods approved by the Project Officer.
 - d) Expand cultures and perform titer analyses in human PBMC cultures in quantities that are sufficient for neutralization assays (see #6) and genetic sequence analysis.
 - e) Identify the virus subtype by heteroduplex mapping analysis (HMA) or other state-of-the-art procedures as approved by the Project Officer.
 - f) Perform genetic sequencing of regions of the virus containing CTL responsive epitopes.
- 10) Establish a database. **(See Note to Offeror # 16)**
 - a) Compile HLA molecular typing data electronically together with CTL and T helper epitopes and virus sequences of relevant epitopes. Align all nucleotide sequence data, translate nucleotide sequence data into amino acid sequences and align. Verify the integrity of genetic sequences by comparing them with known HIV sequences to insure that the sequences produced are HIV-specific and represent the proper gene fragment.
 - b) Analyze immunogenetic, immunologic and virologic data to search for trends with regard to particular HLA alleles

and disease progression or non-progression, and conservation of CTL epitopes within a viral subtype and across viral subtypes.

- c) Transfer all immunogenetic, immunologic, and genetic sequence data into an electronic format compatible with information in the NIAID HIV Database to the NIAID HIV Database and Analysis Unit (HDAU) frequently, and in a manner that ensures data safety and integrity, and work with the HDUA on format from the inception of contract work to ensure data standardization, centralization and compatibility. The Project Officer shall ensure that the data is widely available to the scientific community in a timely manner.

11) Communicate effectively with the Project Officer. **(See Note to Offeror # 17)**

- a) Establish a means of electronic communication with the Project Officer sufficient to support the daily exchange of Email and the submission of data files and reports to the Project Officer when requested.
- b) Ensure a means of communicating with other institutions performing similar activities and develop mechanisms for comparing or pooling data.
- c) Provide quarterly updates of sample acquisition, processing, tests performed and data acquired via fax or Email.
- d) Submit reports in accordance with the Reporting Requirements and Deliverables section incorporated into this RFP.
- e) The Contractor's key personnel shall meet with the Project Officer and the External Advisory Committee assigned to this Contract at the Contractor's site annually to discuss contract data and progress.

12) Maintain a safe worksite, in accordance with the Safety and Health Clause incorporated in this contract, the Offeror's Safety and Health Plan, and all applicable Federal, State, and Local health and safety regulations. The Offeror shall possess and follow a Safety and Health Plan for compliance with all relevant Federal, State, and Local guidelines and regulations regarding exposure to hazardous chemicals drugs and potentially harmful and/or infectious biological materials. **(See Note to Offeror # 18)**

13) Ensure an orderly transition of contract-related materials to a successor Contractor or to the Government.

- a) Six months prior to the expiration date of this contract, a transition plan shall be submitted to the Project Officer for approval.
- b) All original data and selected contract-purchased, Government-titled equipment, shall be delivered by the expiration date of this contract to a location(s) specified by the Project Officer.

14) Any manuscript or scientific meeting abstract containing data generated under this contract shall be submitted for review to the NIAID Project Officer before submission for public presentation or publication. Contract support shall be acknowledged in all such publications. A "publication" is defined as an issue of printed material offered for distribution or any communication or oral presentation of information. The Project Officer will review all manuscripts/abstracts in a period of time not to exceed 15 calendar days from receipt, and will either agree to the publication/ disclosure or recommend changes.

Should patents arise from this contract, they will be subject to federal law governing inventions. Every patent applicant (individual or institutional) is required to provide the Government with a non-exclusive, irrevocable, paid-up license to the invention.

Table 1.

Scientific Area	Experimental Expertise	Anticipated Outcome
Specimen selection	Knowledge of Population Genetics, Epidemiology and Immunogenetics; familiarity with scientific, ethical and managerial issues surrounding acquisition and use of human specimens	Selection and acquisition of a total of 350 HIV+ and 150 HIV- specimens per year from populations suitable for future NIAID-sponsored vaccine trials in international countries within a confined geographic area.
HLA Class I and II Typing	Ability to extract DNA and perform and interpret high and low resolution DNA molecular typing	High (125 samples) and low (300 samples) resolution DNA-based HLA class I typing of human specimens. HLA class II typing (200 samples). Determination of relationship between allele groups and outcome. (See Note # 7 to Offeror)

CD8+ T Lymphocyte Assays	Ability to perform bulk and clonal CTL assays, establish EBV-transformed B lymphoblastoid cell lines, isolate CD8 clones, map epitopes, perform ELISPOT, ICS	Perform 250 CTL assays, establish 250 BLCL lines, and map 200 CTL epitopes per year using state-of-the-art technology. (See Note # 8 and 10 to Offeror)
CD4+ T Lymphocyte Assays	Ability to perform T helper cell function assays, isolate CD4 clones, map epitopes, perform ELISPOT, ICS	Perform 200 proliferation or similar assay and map 100 T helper epitopes per year using state-of-the-art technology. (See Note # 11 to Offeror)
Neutralizing Antibody Assays	Ability to measure neutralizing antibody titers to primary viral isolates in primary cells or transformed cell lines	Perform 800 neutralizing antibody assays with up to 80 viruses of multiple primary and laboratory viral isolates using panels of polyclonal and monoclonal (up to 11) reagents. (See Note # 12 to Offeror)
Virus Sequencing	Ability to isolate and expand HIV-1 and sequence CTL epitope rich regions	Perform virus load on up to 300 specimens/year. Isolate up to 200 virus isolates, expand up to 50 virus isolates, perform HMA analysis on 100 isolates, and genetic sequencing on 300 isolates. Establish a sequence database of conserved and variable viral CTL and T helper epitopes. (See Note # 14 to Offeror)
Database Management	Ability to establish and manage a database in a format compatible with existing NIAID databases. Frequent transfer of data to NIAID HIV Database and Analysis Unit for integration, manipulation and analysis into a comprehensive user-friendly database	Establish a database of HLA types, CTL and T helper epitopes, and viral variants for use by the vaccine research community. Analyze the datasets to look for immunological and virological outcomes and relationships.

Notes To Offerors

HLA Typing and Epitope Mapping Relative to HIV Vaccine Design DAID-03-13

NOTE #1 TO OFFEROR: In responding to this RFP, the Offeror shall describe in detail the responsibilities and level of effort of all proposed personnel who will be assigned to the contract. In addition, the Offeror should describe an administrative framework showing clear lines of authority and a detailed work plan showing proposed time schedules to achieve contract objectives and to maintain quality control over the implementation and operation of the contract. The entire submission (technical, business and appendixes) should not exceed 200 single-spaced and must conform in format to the specifications described in the NIH PHS 398 application.

NOTE #2 TO OFFEROR: Appropriate documentation should include all previous and current projects of a similar nature, including the contract number or grant number, the sponsoring agency, the Project Officer, and a description of the project. The Government is aware that no single organization or institution may have the expertise and facilities required to perform all requirements set forth in this statement of work. Therefore, it may be necessary for the Contractor to subcontract portions of the work. Moreover, since the Government is seeking to support the acquisition of data from potential international vaccine sites, subcontracting to foreign sites is encouraged. Additionally, the relationship between the SubContractor(s) and the prime Contractor in conducting the tasks specified in the statement of work should be clearly delineated. If a SubContractor(s) is proposed, the technical information required by the prime Contractor should be provided about the SubContractor(s) within the Technical Proposal i.e., technical approach, knowledge, methods, experience, personnel qualifications, specific responsibilities and work to be performed for contract, facilities, resources, etc.

NOTE #3 TO OFFEROR: Documentation also should be provided on the qualifications, experience, education, competence, availability, and decision-making authority of the Principal Investigator, Technical and Administrative Support Staffs; the extent to which outside SubContractors/Consultants shall be used and written assurances of their availability, and the percentage of time each staff member (including proposed SubContractors and Consultants) will contribute to the project. Resumes, endorsements, and explanations of previous efforts should clearly demonstrate relevant training, experience, and specific accomplishments.

NOTE #4 TO OFFEROR: A potential source of acquiring specimens shall include, but is not limited to the pool of NIAID grantees funded through the HIV Vaccine Trials Network (the HVTN). For a complete list of sites and principal investigators in the HVTN see <http://www.scharp.org.hvtn/>). A potential site or sites should lie within a related geographic region that is accessible by road or air transportation and does not require overnight transportation of fresh, unfrozen, samples. The Offeror should describe the rationale for site(s) and sample selection, and how the samples shall be delivered to the contract site in a timely manner. The Offeror is strongly encouraged to perform the immunological and virological assays at the site of sample acquisition or at a central laboratory, to minimize transportation of specimens and shipping difficulties, and also to promote technology transfer to international institutions. The need for the Contractor to supply shipping containers will be minimal and will be limited to foreign suppliers who do not have access to such materials. For purposes of preparing a budget, assume shipping receipt and processing of approximately 500 samples/year. Samples shall include, but are not limited to: fresh whole blood (10-15 ml collected in the presence of anti-coagulant and 10-15 ml collected in the absence of anti-coagulant) or frozen tissues including blood cells, serum and plasma, and frozen virus culture supernatants.

NOTE #5 TO OFFEROR: The Offeror shall include in the Technical Proposal details of a proposed specimen-tracking database. The Offeror shall describe a computerized mechanism for recording receipt, status and location of samples, and a plan for a quarterly notification to the Project Officer of samples received in the preceding months, including but not limited to sites from which samples were received, dates samples were received, and a description of the condition of samples upon receipt. The database format shall be compatible with existing NIAID databases.

NOTE #6 TO OFFEROR: The Offeror shall submit in the Technical Proposal a detailed protocol for molecular typing of HLA class I and II. All HLA Laboratory typing protocols must comply with the American Society of Histocompatibility and Immunogenetics (ASHI) gold standard regulations. The Offeror is encouraged to utilize novel technology such as DNA arrays to optimize HLA typing for high throughput vaccine efficacy trials.

NOTE #7 TO OFFEROR: For purposes of preparing a budget, the Offeror should assume class I typing of approximately 225 HIV+ samples and 75 HIV- samples by low resolution, and 100 HIV+ and 25 HIV- samples by high resolution per year. For class II typing assume approximately 150 HIV+ samples and 50 HIV- samples.

NOTE #8 TO OFFEROR: The Offeror shall describe in detail his/her technical approaches for evaluating CTL responses by providing current SOPs, as well as relevant peer reviewed published papers. These SOPs should include a description of the experimental design (sequence in which various types of studies will be carried out), and a description of the methods to carry out evaluations. A rationale for the design, based on statistical considerations, if appropriate, should be provided as well as a discussion of potential logistical problems and possible solutions. Many of the required reagents are available through the AIDS Research and Reference Repository (operated by McKesson BioServices, 621 Lofstrand Lane, Rockville, MD 20850). For purposes of preparing a budget, the Offeror shall assume that CTL assays will be carried out on 250 samples/year and 250 BLCL lines need to be produced/year.

NOTE #9 TO OFFEROR: The Offeror shall describe in detail their technical approaches for evaluating cellular immune responses by providing current SOPs, as well as peer reviewed published papers. These SOPs should include a description of the experimental design (sequence in which various types of studies will be carried out), and a description of the methods to carry out evaluations. A rationale for the design, based on statistical considerations, if appropriate, should be provided as well as a discussion of potential logistical problems and possible solutions. Many of the required reagents are available through the AIDS Research and Reference Repository (operated by McKesson BioServices, 621 Lofstrand Lane, Rockville, MD 20850). For purposes of preparing a budget, the Offeror shall assume that ELISPOT assays will be carried out on 200 samples/year. The Offeror should submit information pertaining to development of new assays, or adaptation of assays for large-scale use, but costs for performing the assays should not be included in the cost estimate. For QA/QC testing of cellular immune assays, the Project Officer will co-ordinate the acquisition and supply of appropriate samples from DAIDS-supported clinical networks. For purposes of preparing a budget, the Offeror shall assume that proficiency testing will occur bi-annually with panels of about 10 coded specimens.]

NOTE #10 TO OFFEROR: The Contractor shall devise and propose a scheme for deciding the order and process for mapping CTL epitopes restricted by the most common HLA alleles. For purposes of preparing a budget, the Offeror should plan on mapping 200 CTL epitopes /year.

NOTE #11 TO OFFEROR: The Contractor shall devise and propose a scheme for deciding the order in which to perform T helper cell assays and for mapping T helper epitopes. For purposes of preparing a budget, the Offeror should plan on performing 200 proliferation or similar type assays and mapping 100 helper epitopes /year.

NOTE #12 TO OFFEROR: The Offeror shall describe in detail his/her technical approach for evaluating neutralizing antibody responses by providing a currently used protocol, as well as peer reviewed published papers. The Offeror is encouraged to refine existing assays and investigate new technologies for the evaluation of primary isolate neutralization. This protocol should include a description of the experimental design (sequence in which various types of studies will be carried out), and a description of the methods to carry out evaluations. A rationale for the design, based on statistical considerations, if appropriate, should be provided as well as a discussion of potential logistical problems and possible solutions. For purposes of preparing a budget, the Offeror shall assume neutralization analysis of approximately 80 virus isolates testing 10 antisera or other reagents per isolate, for a total of 800 neutralizing assays /year.

NOTE #13 TO OFFEROR: At the present time it is assumed that these assays are not feasible for use on a large-scale basis to measure virus neutralization. The Offeror should submit information pertaining to development of new assays, or adaptation of assays for large-scale use, but costs for performing the assays should not be included in the cost estimate.

NOTE #14 TO OFFEROR: In the technical proposal, the Offeror shall provide sample protocols together with documentation of their experience in performing these protocols, for example, peer reviewed papers. For the purposes of preparing a budget, the Offeror shall assume that virus load measurements will be carried out on 300 specimens/year, virus isolation attempts will be carried out on 200 samples/year, that virus expansions will be required for approximately 50 isolates/year, that HMA analysis will be conducted on 100 isolates/year, and that genetic sequencing will be conducted on 300 isolates/year.

NOTE #15 TO OFFEROR: The Contractor shall devise and propose a scheme for selecting specimens for HIV virus load measurements and isolation. Final sample selection should occur in consultation with the Project Officer.

NOTE #16 TO OFFEROR: The Offeror should contact the PI of the HDAU to obtain pertinent information about the coordinates of existing HIV databases at <http://hiv-web.lanl.gov/>. All providers of samples and investigators contributing directly to the data generation will be cited, either by authorship or acknowledgement of their contributions. The data will remain the property of NIAID. In addition, sequence data and viral clones obtained through this Contract may be made available by the Project Officer to vaccine manufacturers as needed.

NOTE #17 TO OFFEROR: The Contractor and all key personnel will be subject to an annual review of performance by an External Advisory Committee, as described under the “Reporting Requirements” section of this RFP. The membership of the external Advisory Committee will be jointly proposed and agreed to by the Contractor and the NIH. The Contractor will convene the External Advisory Committee and will pay travel expenses of the Committee.

NOTE #18 TO OFFEROR: The Safety and Health Clause of this solicitation should be consulted for additional information. The plan shall include discussions of such topics as training and monitoring of personnel, the use of protective garments and equipment by personnel, and protocols for dealing with chemical and biological spills and accidents. A copy of the plan shall be submitted in an appendix to the Technical Proposal.

Reporting Requirements
HLA Typing and Epitope Mapping Relative to HIV Vaccine Design
RFP DAID-03-13

The Contractor shall provide quarterly sample acquisition reports as well as 2 semi-annual reports per year that include, at a minimum, the information specified below. All reports shall be submitted as hard copies, and in electronic form, as computer files, in Microsoft Word™ version 7.0 for Windows and Microsoft Excel™ version 7.0 for Windows, with formats readable with an IBM-type personal computer. Files shall be sent by Email or on 3.5 inch discs by US mail or courier service. All reports shall be archived on 3.5 inch discs or other appropriate media for surrender to the Government at the expiration of the contract.

1) Quarterly Sample Acquisition Reports

The Contractor shall submit quarterly reports that summarize the following:

An inventory of samples acquired, type of sample, source of sample, geographic locale from which sample was derived; an inventory of all reagents derived from each sample, including amplified DNA and clones derived; a report of all genetic analyses carried out on each sample; HLA analyses performed; CD8+ or CD4+ T cell assays conducted; neutralizing antibody responses; summary of laboratory results, and an inventory of samples sent out to collaborating laboratories.

2) Semi Annual Reports

The Contractor shall submit semi-annual reports that summarize the studies completed by the Contractor in the preceding 6 month period. Semi-annual reports shall be composed of:

- a) A cover page containing:
 - i) Contract title and number
 - ii) Period of performance being reported
 - iii) Contractor's name and address
 - iv) Date of submission.
- b) A table of contents.
- c) Summary tables of results during the preceding 6 month period.
- d) A discussion of technical and administrative problems encountered, their resolution or proposed corrective action; explanation of differences between planned progress and actual progress.

An inventory of samples received, type of sample, source of sample, geographic locale from which sample was derived; an inventory of all reagents derived from each sample, including amplified DNA and clones derived; a report of all genetic analyses carried out on each sample; HLA analysis performed; CD8+ or CD4+ assays conducted; neutralizing antibody responses; and an inventory on all samples sent out to collaborating laboratories.

Selected other additional information as may be required by the Project Officer.

3) Sequence data and alignments transfer via electronic mail or computer diskette:

- a) At the time of submission of each report the Contractor shall submit via electronic mail or computer diskette all sequence data, and all nucleotide and amino acid alignments generated during that reporting period. The Project Officer will determine choice of transfer. Diskettes shall be formatted and data recorded in a format specified by the Project Officer.

4) A cumulative list of oral presentations and published materials attributable to the contract.

5) The final semi-annual report shall contain additionally:

- a) a brief description of any unfinished projects.
- b) a status report on transition or shut down activities.

6) Annual Site Visit

During the final quarter of each contract year, the Contractor shall host, for NIAID contract and program staff, and their External Advisory Committee, a site visit review. This meeting shall be attended by the Contractor's principal investigator and all co-investigators. These presentations shall include summaries of all goals or milestones reached during the review period and include a description of all problems encountered that will impact the achievement of particular goals as outlined in the Contractor's research plan. The Principal Investigator, co-investigator and staff representing each project and sub-project shall describe goals and objectives for the coming year. Additionally, application of the policies and procedures for monitoring the direction of specific projects shall be presented. A report of the plan for, and results of, this site visit shall be prepared by the Contractor and submitted to the Project Officer (in hard copy and digital medium) and the Contracting Officer (original hard copy).

7) Distribution

It remains the responsibility of the Contractor to assure receipt by the Government official listed below of all deliverables by the established due dates. If the Contractor is unable to deliver the items specified hereunder within the period of performance, notwithstanding the exercise of good faith and diligent efforts in performance of the work, the Contractor shall give the Contracting Officer immediate written notice of anticipated delays with reasons therefore.

Type of Deliverable	No. of Copies	Addressee/Distribution	Due Dates
Quarterly Report	1	Project Officer, Contracting Officer	Within 10 calendar days after each 3 month period from the time of contract award
Semi-Annual Report	1	Project Officer, Contracting Officer	Within 15 calendar days after each 6 month period from the time of contract award
	1	Contracting Officer	
Final Semi-Annual Report	1	Project Officer, Contracting Officer	Within 30 calendar days after the final month of the contract
	1	Contracting Officer	

PART I - THE SCHEDULE

SECTIONS B - H -- UNIFORM CONTRACT FORMAT - GENERAL

A Sample Uniform Contract Format may be found at the following website:

<http://www4.od.nih.gov/ocm/contracts/rfps/sampkt.htm>

[Disregard SECTION I and J of this sample. Those SECTIONS have been incorporated as part of this RFP.]

PART II – CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

THE FOLLOWING PAGES CONTAIN A LISTING(S) OF GENERAL CLAUSES WHICH WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSES LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP.

BECAUSE THIS IS A STREAMLINED RFP, ARTICLES I.2. AND I.3., WHICH IDENTIFY ANY AUTHORIZED ADDITIONS, SUBSTITUTIONS AND/OR MODIFICATIONS TO THE GENERAL CLAUSES, WILL BE BASED ON THE TYPE OF CONTRACT/CONTRACTOR AND WILL BE DETERMINED DURING NEGOTIATIONS.

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT – FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this URL: <http://www.arnet.gov/far/>.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CHAPTER 1) CLAUSES

FAR

<u>Clause No.</u>	<u>Date</u>	<u>Title</u>
52.202-1	Dec 2001	Definitions
52.203-3	Apr 1984	Gratuities (Over \$100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over \$100,000)
52.203-6	Jul 1995	Covenant Against Contingent Fees (Over \$100,000)
52.203-7	Jul 1995	Anti-Kickback Procedures (Over \$100,000)
52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over \$100,000)
52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over \$100,000)
52.203-12	Jun 1997	Limitation on Payments to Influence Certain Federal Transactions (Over \$100,000)
52.204-4	Aug 2000	Printing/Copying Double-Sided on Recycled Paper (Over \$100,000)
52.209-6	Jul 1995	Protecting the Governments Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over \$25,000)
52.215-2	Jun 1999	Audit and Records - Negotiation (Over \$100,000)
52.215-8	Oct 1997	Order of Precedence – Uniform Contract Format
52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data
52.215-12	Oct 1997	Subcontractor Cost or Pricing Data (Over \$500,000)
52.215-14	Oct 1997	Integrity of Unit Prices (Over \$100,000)
52.215-15	Dec 1998	Pension Adjustments and Asset Reversions
52.215-18	Oct 1997	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) Other Than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications
52.216-7	Feb 2002	Allowable Cost and Payment
52.216-8	Mar 1997	Fixed Fee
52.219-8	Oct 2000	Utilization of Small Business Concerns (Over \$100,000)

52.219-9	Jan 2002	Small Business Subcontracting Plan (Over \$500,000)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over \$500,000)
52.222-2	Jul 1990	Payment for Overtime Premium (Over \$100,000) (NOTE: The dollar amount in paragraph (a) of this clause is \$0 unless otherwise specified in the contract.)
52.222-3	Aug 1996	Convict Labor
52.222-26	Feb 1999	Equal Opportunity
52.222-35	Dec 2001	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
52.222-37	Dec 2001	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.223-6	May 2001	Drug-Free Workplace
52.223-14	Oct 2000	Toxic Chemical Release Reporting
52.225-1	Feb 2002	Buy American Act - Balance of Payments Program – Supplies
52.225-13	Jul 2000	Restrictions on Certain Foreign Purchases
52.227-1	Jul 1995	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over \$100,000)
52.227-11	Jun 1997	Patent Rights - Retention by the Contractor (Short Form) (NOTE: In accordance with FAR 27.303 (a) (2), paragraph (f) is modified to include the requirements in FAR 27.303 (a) (2) (i) through (iv). The frequency of reporting in (i) is annual.
52.227-14	Jun 1987	Rights in Data – General
52-232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	Jun 1996	Interest (Over \$100,000)
52.232-20	Apr 1984	Limitation of Cost
52.232-23	Jan 1986	Assignment of Claims
52.232-25	Feb 2002	Prompt Payment
52.232-34	May 1999	Payment by Electronic Funds Transfer--Other Than Central Contractor Registration
52.233-1	Dec 1998	Disputes
52.233-3	Aug 1996	Protest After Award
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-3	May 2001	Penalties for Unallowable Costs (Over \$500,000)
52.242-4	Jan 1997	Certification of Final Indirect Costs

52.242-13	Jul 1995	Bankruptcy (Over \$100,000)
52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
52.244-2	Aug 1998	Subcontracts, Alternate II (Aug 1998) *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B., Advance Understandings.
52.244-5	Dec 1996	Competition in Subcontracting (Over \$100,000)
52.245-5	Jan 1986	Government Property (Cost-Reimbursement, Time and Material, or Labor Hour Contract)
52.246-23	Feb 1997	Limitation of Liability (Over \$100,000)
52.249-6	Sep 1996	Termination (Cost-Reimbursement)
52.249-14	Apr 1984	Excusable Delays

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES

<u>HHSAR Clause No.</u>	<u>Date</u>	<u>Title</u>
352.202-1	Jan 2001	Definitions - with Alternate paragraph (h) (Jan 2001)
352.228-7	Dec 1991	Insurance - Liability to Third Persons
352.232-9	Apr 1984	Withholding of Contract Payments
352.233-70	Apr 1984	Litigation and Claims
352.242-71	Apr 1984	Final Decisions on Audit Findings
352.270-5	Apr 1984	Key Personnel
352.270-6	Jul 1991	Publication and Publicity

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following Attachments are provided in full text with this Solicitation:

PACKAGING AND DELIVERY OF PROPOSALS (Attached to this listing)

HOW TO PREPARE AN ELECTRONIC PROPOSAL: (Attached to this listing)

PROPOSAL INTENT RESPONSE SHEET [SUBMIT ON/BEFORE: August 16, 2002] (Attached to this listing)

[NOTE: Your attention is directed to the "Proposal Intent Response Sheet". If you intend to submit a proposal, you must complete this form and return it to this office via fax or e-mail on or before the date identified above. The receipt of this form is critical as it contains information essential for CMB's coordination of the electronic submission and review of proposals.]

RFP FORMS AND ATTACHMENTS:

THE RFP FORMS/ATTACHMENTS LISTED BELOW ARE AVAILABLE IN A VARIETY OF FORMATS AND MAY BE VIEWED OR DOWNLOADED DIRECTLY FROM THIS SITE:

<http://www.niaid.nih.gov/contract/ref.htm>

APPLICABLE TO TECHNICAL PROPOSAL (INCLUDE THESE DOCUMENTS/FORMS WITH YOUR TECHNICAL PROPOSAL):

- **Technical Proposal Cover Sheet**
- **Technical Proposal Cost Information**
- **Summary of Related Activities**
- **Government Notice for Handling Proposals**

APPLICABLE TO BUSINESS PROPOSAL (INCLUDE WITH YOUR BUSINESS PROPOSAL):

- **NIH-2043, Proposal Summary and Data Record**
- **Small Business Subcontracting Plan Format *[if applicable]***
- **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours**
- **Offeror's Points of Contact**

TO BECOME CONTRACT ATTACHMENTS (INFORMATION ONLY):

- **NIH(RC)-4: Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts**
- **NIH(RC)-7: Procurement of Certain Equipment, (OMB Bulletin 81-16)**
- **Safety and Health, HHSAR Clause 352.223-70**
- **Privacy Act System of Records**
- **Report of Government Owned, Contractor Held Property**
- **Disclosure of Lobbying Activities, OMB Form LLL**

PACKAGING/DELIVERY/ELECTRONIC SUBMISSION OF THE PROPOSAL

Listed below are delivery instructions for the submission of both PAPER and ELECTRONIC COPIES of your proposal.

PAPER SUBMISSION: The paper copy is the official copy for recording timely receipt of proposals. You are required to submit one original paper copy of your proposal along with the number of extra copies required below.

ELECTRONIC SUBMISSION: In addition to the paper submission, you are required to submit your proposal electronically through the CRON (Contracts Review Online) in accordance with the instructions provided below. If you experience difficulty or are unable to transmit, you should submit your proposal on a CD-Rom or ZipDisk by an express delivery service. We can then upload your proposal into the electronic system. You must certify that both the original paper and electronic versions of the proposal are identical.

SUBMISSION OF PROPOSALS BY FACSIMILE IS NOT ACCEPTABLE.

Shipment and marking of paper copies shall be as indicated below:

A. EXTERNAL PACKAGE MARKING:

In addition to the address cited below, mark each package as follows:

"RFP NO. NIH-NIAID-DAIDS-03-13

TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

B. NUMBER OF COPIES:

The number of copies required of each part of your proposal are as specified below.

Technical Proposal: One (1) unbound signed original and five (5) unbound copies. Ten (10) copies of all material not available electronically (i.e. SOPs, Pertinent Manuals, Nonscannable Figures or Data, and Letters of Collaboration/Intent).

Business Proposal: One (1) unbound signed original and 5 unbound copies.

C. PAPER COPIES and CD-Rom or ZipDisk to:

If Hand Delivery or Express Service	If using U.S. Postal Service
Scott Drega Contract Specialist Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230 Bethesda, Maryland 20817	Scott Drega Contract Specialist Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230, MSC 7612 Bethesda, Maryland 20892-7612

NOTE: All material sent to this office by Federal Express should be sent to the Hand Carried Address.

NOTE: The U.S. Postal Service's "Express Mail" does not deliver to the hand delivered (20817 zip code) address. Any package sent to this address via this service will be held at a local post office for pick-up. THE GOVERNMENT IS NOT RESPONSIBLE FOR PICKING UP ANY MAIL AT A LOCAL POST OFFICE. If a proposal is not received at the place, date, and time specified herein, it will be considered a "late proposal," in accordance with HHSAR 352.215-70, Late Proposals and Revisions (NOV 1986).

HOW TO PREPARE AND SUBMIT AN ELECTRONIC PROPOSAL

PAGE LIMITS -- THE TECHNICAL PROPOSAL IS LIMITED TO NOT-TO-EXCEED Two-hundred (200) PAGES [INCLUDING: Appendices, Attachments, Operating Manuals, Non-Scannable Figures or Data, Letters of Intent, etc.] with the NARRATIVE PORTION OF THE TECHNICAL PROPOSAL LIMITED TO NOT-TO-EXCEED Fifty (50) PAGES. ANY PORTIONS OF YOUR PROPOSAL NOT AVAILABLE ELECTRONICALLY ARE ALSO CONSIDERED TO BE INCLUDED IN THE TOTAL PAGE LIMITATION. PAGES IN EXCESS OF THIS LIMITATION WILL BE REMOVED FROM THE PROPOSAL AND WILL NOT BE READ OR EVALUATED.

Note that although no page limit has been placed on the Business Proposal, offerors are encouraged to limit its content to only those documents necessary to provide adequate support for the proposed costs.

ELECTRONIC SUBMISSION – To submit a proposal electronically under this RFP, offerors will need to prepare the proposal on a word processor or spreadsheet program (for the business portion) and convert them to Adobe Acrobat Portable Document Format (.pdf). THE TECHNICAL PROPOSAL AND BUSINESS PROPOSAL MUST BE CONTAINED ON SEPARATE FILES which must be identified as either TECHNICAL or BUSINESS and include some recognizable portion of the ORGANIZATION NAME.

Please note that the electronic submission does not replace the requirement to submit a signed, unbound original paper copy of both your Technical and Business Proposal, along with any required unbound duplicate copies. These paper originals should be mailed or hand-delivered to the address provided in this attachment and must be received on/before the closing date and time.

There is no limit to the size (MB) of the two electronic PDF files to be submitted; however, the size of the technical proposal is limited to the page limitation language outlined above. For purposes of assessing compliance with the page count, technical proposals will be viewed using the print function of the Adobe Acrobat Reader, Version 4.0 (or higher).

Formatting Requirements:

- Do not embed sound or video (e.g., MPEG) files into the proposal documents. The evaluation system does not have the capability to read these files.
- Keep graphics embedded in documents as simple as possible. Complex graphics require longer periods for the computers used in the evaluation system to draw, and redraw these figures and scrolling through the document is slowed significantly.
- Type density and size must be 10 to 12 points. If constant spacing is used, there should be no more than 15 cpi, whereas proportional spacing should provide an average of no more than 15 cpi. There must be no more than six lines of text within a vertical inch. Margins must be set to 1 inch around.
- Paper size should not exceed 8-1/2 x 11. Larger paper sizes will be counted as 2 pages.
- Limit colors to 256 colors at 1024 x 768 resolution; avoid color gradients.
- Simplify the color palette used in creating figures.
- Be aware of how large these graphics files become. Large files are discouraged.
- Limit scanned images as much as possible.
- Limit appendices and attachments to relevant technical proposal information (e.g., SOPs, pertinent manuals, non-scannable figures or data, resumes, letters of commitment/intent).

SUBMISSION OF “PROPOSAL INTENT TO RESPOND SHEET”:

Approximately TWO weeks prior to the due date of the proposals, all offerors who submitted a “Proposal Intent Response Sheet” will be provided with specific electronic access information and electronic proposal transmission instructions. For this reason, it is imperative that all offerors who are intending to submit a proposal in response to this RFP contact the Contract Specialist identified in this RFP and complete and submit the attached “Proposal Intent Response Sheet” by the date provided on that Attachment.

CREATE ADOBE PDF ONLINE -- Adobe will allow you to create 5 documents on a trial for free. If you want to use the site regularly it costs \$10/month or \$100/year. Please link to the following URL for information:

<https://createpdf.adobe.com/index.pl/3847995518.39272?BP=IE>

LOG-IN / TRANSMISSION INSTRUCTIONS:

1. Log-in Site: Will be provided by the Contract Specialist after receipt of the "Proposal Intent Response Sheet"
2. Log-in Name: Will be provided by the Contract Specialist.
3. Log-in Password: Will be provided via telephone by the Contract Specialist after Log-in Name is provided.
4. Procedure -- When your proposal is completed and converted to a PDF file using Adobe Acrobat, it is ready to be transmitted electronically. You must upload separate Technical and Business Proposal Files. It is recommended that proposals be transmitted a few days before the due date so that you will have sufficient time to overcome any transmission difficulties.
 - You must have Explorer 3.1 or higher.
 - It is essential that you use antiviral software to scan all documents.
 - Click on "Sign On" and enter your log-in name and password.
 - Click on "Browse" to locate your saved files on your computer.
 - Click on "Upload Proposal" after you have located the correct file.
 - After a file is uploaded, a link to the file will appear under "Upload Files" at the bottom of the screen. Click on that link to view the uploaded file.
 - If you experience difficulty in accessing your documents, please contact the appropriate NIH contracts office immediately.
 - If you wish to revise your proposal before the closing date and time, simply log in again and re-post.

USER ACCESS TO THE POSTING SITE WILL BE DENIED AFTER THE RFP CLOSING DATE AND TIME PROVIDED WITH THIS RFP OR ITS MOST RECENT AMENDMENT(S).

PROPOSAL INTENT RESPONSE SHEET

RFP No.: NIH-NIAID-DAIDS-03-13

RFP Title: HLA Typing and Epitope Mapping Relative To HIV Vaccine Design

Please review the attached Request for Proposal. Furnish the information requested below and return this page by August 16, 2002. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

Since your proposal will be submitted electronically, please include the name and e-mail of the individual to whom the electronic proposal instructions, login code, and password should be provided.

☐ DO INTEND TO SUBMIT A PROPOSAL

☐ DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASONS:

Company/Institution Name (print): _____

Address (print): _____

Project Director's Name (print): _____

Title (print): _____

Signature/Date: _____

Telephone Number and E-mail Address (print clearly):

***Name of individual to whom electronic proposal instructions should be sent:**

Name: _____

Title: _____

E-Mail Address: _____

Telephone Number: _____

Names of Collaborating Institutions and Investigators (include Subcontractors and Consultants) (print):

(Continue list on a separate page if necessary)

RETURN VIA FAX OR E-MAIL TO:

CMB, NIAID, NIH

Room 2230

6700-B Rockledge Drive, MSC 7612

Bethesda, MD 20892-7612

Attn: Scott Drega

RFP-NIH-NIAID-DAIDS-03-13

FAX# (301) 480-5253

Email : sdrega@niaid.nih.gov

PART IV – REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

Representations, Certifications, and Other Statements of Offerors or Quoters (Negotiated).

1. REPRESENTATIONS AND CERTIFICATIONS

The Representations and Certifications required by this particular acquisition can be accessed electronically from the INTERNET at the following address:

<http://rcb.nci.nih.gov/forms/rcneg.pdf>

If you are unable to access this document electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST COMPLETE THE REPRESENTATIONS AND CERTIFICATIONS AND SUBMIT THEM AS PART OF YOUR BUSINESS PROPOSAL.

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

a. INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION [FAR Clause 52.215-1 (May 2001)]

(a) *Definitions.* As used in this provision--

Discussions are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

"*In writing*", "writing", or "*written*" any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

"*Proposal modification*" is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

"*Proposal revision*" is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

"*Time*," if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) *Amendments to solicitations.* If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) *Submission, modification, revision, and withdrawal of proposals.* (1) Unless other methods (e.g., electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show--

- (i) The solicitation number;
- (ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);
- (iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;
- (iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and
- (v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) *Submission, modification, revision, and withdrawal of proposals.* (i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

- (ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it

is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

- (1) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or
- (2) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or
- (3) It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.

- (iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.
- (iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.
- (v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

(4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.

(5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.

(6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.

(7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.

(8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

(d) *Offer expiration date.* Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

[Note: In accordance with HHSAR 352.215-1, the following paragraph (e) is substituted for the subparagraph (e) of the provision at FAR 52.215-1.]

(e) *Restriction on disclosure and use of data.* (1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act. The legend reads:

Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.

The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.

If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.

The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

- (2) In addition, the offeror should mark each page of data it wishes to restrict with the following statement:

“Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation.”

- (3) Offerors are cautioned that proposals submitted with restrictive legends or statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.

- (f) *Contract award.* (1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

- (2) The Government may reject any or all proposals if such action is in the Government's interest.

- (3) The Government may waive informalities and minor irregularities in proposals received.

- (4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

- (5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.

- (6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.

- (7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.

- (8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.
- (9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.
- (10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.
- (11) The Government may disclose the following information in postaward debriefings to other offerors:
 - (i) The overall evaluated cost or price and technical rating of the successful offeror;
 - (ii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;
 - (iii) A summary of the rationale for award; and
 - (iv) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.

Alternate I (October 1997). As prescribed in 15.209(a)(1), substitute the following paragraph (f)(4) for paragraph (f)(4) of the basic provision:

(f) (4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.

b. NAICS CODE AND SIZE STANDARD

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Section K of this RFP), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

- (1) The North American Industry Classification System (NAICS) code for this acquisition is 54171.
- (2) The small business size standard is 500 employees.

THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS. However, the Federal Acquisition Regulation (FAR) requires in every solicitation, (except for foreign acquisitions) the inclusion of the North American Industry Classification System (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

c. NOTICE OF PRICE EVALUATION ADJUSTMENT FOR SMALL DISADVANTAGED BUSINESS CONCERNS

In accordance with FAR Clause 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns, incorporated in Section I.3., offerors will be evaluated by adding a factor of 10 percent to the price of all offers, except offers from small disadvantaged business concerns that have not waived the adjustment. (Note: A listing of other offerors who are excepted and will not have this evaluation factor added to their offer may be found in subparagraph (b) of FAR Clause 52.219-23.

A small disadvantaged business concern may elect to waive the adjustment, in which case the factor will be added to its offer for evaluation purposes. The agreements in paragraph (d) of FAR Clause 52.219-23 do not apply to offerors that waive the adjustment.

AN OFFEROR WHO ELECTS TO WAIVE THIS EVALUATION ADJUSTMENT MUST SPECIFICALLY INDICATE WITH A STATEMENT TO THIS EFFECT ON THE COVER PAGE OF ITS BUSINESS PROPOSAL.

d. TYPE OF CONTRACT AND NUMBER OF AWARD(S)

It is anticipated that ONE AWARD will be made from this solicitation and that the award(s) will be made on/about May 8, 2003.

It is anticipated that the award(s) from this solicitation will be a multiple-year COST REIMBURSEMENT type COMPLETION contract with a PERIOD OF PERFORMANCE OF Five (5) years, and that incremental funding will be used [see Section L.2.c. Business Proposal Instructions].

e. ESTIMATE OF EFFORT

It is expected that a completion type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the effort to be as stated below. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

<u>Position</u>	<u>Percent Effort Per Year</u>
Principal Investigator	10%
Co-Principal Investigator	40%
Project Manager	25%
Sr. Scientist (Immunogenetics)	50%
Project Manager	50%
Sr. Scientist (Immunology)	50%
Project Manager	50%
Sr. Scientist (Virology)	50%
Data Manager	50%
Site Coordinator	100%
Technical Support	100%
Technical Support	100%
Technical Support	75%

f. COMMITMENT OF PUBLIC FUNDS

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

g. COMMUNICATIONS PRIOR TO CONTRACT AWARD

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

h. RELEASE OF INFORMATION

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

i. **COMPARATIVE IMPORTANCE OF PROPOSALS**

You are advised that paramount consideration shall be given to the evaluation of technical proposals. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. The relative importance of the evaluation factors is specified in SECTION M of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

j. **PREPARATION COSTS**

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

k. **SERVICE OF PROTEST (AUGUST 1996) - FAR 52.233-2**

- (a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the General Accounting Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Brenda J. Velez
Contracting Officer
Contract Management Branch, DEA
National Institute of Allergy and Infectious Diseases
6700-B Rockledge Drive, Room 2230, MSC 7612
BETHESDA MD 20892-7612

- (b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

l. **LATE PROPOSALS AND REVISIONS, HHSAR 352.215-70**

Notwithstanding the procedures contained in FAR 52.215-1(c)(3) of the provision of this solicitation entitled Instructions to Offerors—Competitive Acquisition, a proposal received after the date specified for receipt may be considered if it offers significant cost or technical advantages to the Government; and it was received before proposals were distributed for evaluation, or within five calendar days after the exact time specified for receipt, whichever is earlier.

m. **AVAILABILITY OF THE "FEDERAL ADP AND TELECOMMUNICATIONS STANDARDS INDEX."**

Copies of the "Federal ADP and Telecommunications Standards Index" can be purchased from the U.S. Government Printing Office, Superintendent of Documents, Washington, DC 20402.

n. **USE OF INTERNET WEB SITE ADDRESSES (URLs) IN PROPOSALS**

Unless otherwise specified or required in NIAID solicitations, internet Web Site addresses (URLs) may not be used to provide information necessary to the conduct of the review of the proposal. Direct access to an internet site by a Reviewer who is examining and reviewing the proposal on behalf of the NIAID could compromise their anonymity during the review process. If a URL contains information pertinent to the proposal content, the offeror must provide access to the website via a temporary website portal which allow reviewers the capability to view and interact with the site.

The proposal must clearly identify the URLs to be accessed and the procedure for accessing the temporary website portal. Access must not require the identity of the individual.

2. INSTRUCTIONS TO OFFERORS

GENERAL INSTRUCTIONS

INTRODUCTION

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

(1) Contract Type and General Clauses

It is contemplated that a cost-reimbursement completion type contract will be awarded. (See General Information) Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

(2) Authorized Official and Submission of Proposal

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

Include RFP title, number, name of organization, identification of the proposal part, and indicate whether the proposal is an original or a copy.

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments.

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments.

(3) Proposal Summary and Data Record (NIH-2043)

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See Section J, Attachment entitled, PROPOSAL SUMMARY AND DATA RECORD).

(4) Separation of Technical and Business Proposals

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See Attachment entitled, TECHNICAL PROPOSAL COST INFORMATION/SUMMARY OF LABOR AND DIRECT COSTS).) However, the technical proposal should **not** include pricing data relating to individual salary information, indirect cost rates or

amounts, fee amounts (if any), and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

(5) Alternate Proposals

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

(6) Evaluation of Proposals

The Government will evaluate technical proposals in accordance with the criteria set forth in PART IV, SECTION M of this RFP.

(7) Potential Award Without Discussions

The Government reserves the right to award a contract without discussions if the Contracting Officer determines that the initial prices are fair and reasonable and that discussions are not necessary.

(8) Use of the Metric System of Measurement

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

Hard Metric - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

(9) Human Subjects

IMPORTANT NOTE TO OFFERORS: The following 6 paragraphs [(9) through (14)] shall be addressed in a SEPARATE SECTION of the Technical Proposal entitled, "HUMAN SUBJECTS."

The following notice is applicable when contract performance is expected to involve risk to human subjects:

Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects (JANUARY 2001)

- a) Copies of the Department of Health and Human Services (Department) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office of Protection from Research Risks (OPRR), National Institutes of Health (NIH), Bethesda, Maryland 20892*. The regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the Department.

- b) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information. The regulations extend to the use of human organs, tissue and body fluids from individually identifiable human subjects as well as to graphic, written or recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR, Part 46.
- c) Activities in which the only involvement of human subjects will be in one or more of the categories set forth in 45 CFR 46.101(b)(1-6) are exempt from coverage.
- d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal. The National Institutes of Health will make a final determination of whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the proposal. In doubtful cases, prior consideration with OPRR*, (telephone: 301-496-7014*), is recommended.
- e) In accordance with 45 CFR, Part 46, prospective Contractors being considered for award shall be required to file with OPRR* an acceptable Assurance of Compliance with the regulations, specifying review procedures and assigning responsibilities for the protection of human subjects. The initial and continuing review of a research project by an institutional review board shall assure that the rights and welfare of the human subjects involved are adequately protected, that the risks to the subjects are reasonable in relation to the potential benefits, if any, to the subjects and the importance of the knowledge to be gained, and that informed consent will be obtained by methods that are adequate and appropriate. Prospective Contractors proposing research that involves human subjects shall be contacted by OPRR* and given detailed instructions for establishing an institutional review board and filing an Assurance of Compliance.
- f) It is recommended that OPRR* be consulted for advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects. (End of Provision)

**Note: The Office for Human Research Protections (OHRP), Office of the Secretary (OS), Department of Health and Human Services (DHHS) is the office responsible for oversight of the Protection of Human subjects and should replace Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH) wherever it appears in this provision. The phone number to reach this office is 301-496-7014. For more information, the OHRP website may be accessed at <http://ohrp.osophs.dhhs.gov/> Copies of the DHHS Regulations for the Protection of Human Subjects, 45 CFR Part 46, are also available on line at http://www.access.gpo.gov/nara/cfr/waisidx_01/45cfr46_01.html.*

(10) Instructions to Offerors Regarding Protection of Human Subjects

*****(Note: The requirements in this paragraph (10), may be supplemented when necessary, based on the specific requirements of the solicitation.) *****

Offerors must address the following human subjects protections issues if this contract will be for research involving human subjects (note: under each of the following points below, the offeror should indicate whether the information provided relates to the primary research site, or to a collaborating performance site(s), or to all sites:

(a) Risks to the subjects

Human Subjects Involvement and Characteristics:

- Describe the proposed involvement of human subjects in response to the solicitation.
- Describe the characteristics of the subject population, including their anticipated number, age range, and health status.
- Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as fetuses, pregnant women, children, prisoners, institutionalized individuals, or others who are likely to be vulnerable populations.

Sources of Materials:

- Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

Potential Risks:

- Describe the potential risks to subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness to the subjects.
- Describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures, to participants in the proposed research, where appropriate.

(b) Adequacy of Protection Against Risks

Recruitment and Informed Consent:

- Describe plans for the recruitment of subjects and the procedures for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. The informed consent document for the contractor and any collaborating sites should be submitted only if requested elsewhere in the solicitation. Be aware that an IRB-approved informed consent document for the contractor and any participating collaborative sites must be provided to the Government prior to patient accrual or participant enrollment.

Protection Against Risk:

- Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness.
- Discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects where appropriate.
- In studies that involve interventions, describe the provisions for data and safety monitoring of the research to ensure the safety of subjects.

(c) Potential Benefits of the Proposed Research to the Subjects and Others

- Discuss the potential benefits of the research to the subjects and others.
- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.
- Describe treatments and procedures that are alternatives to those provided to the participants by the proposed research, where appropriate.

(d) Importance of the Knowledge to be Gained

- Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.
- Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that may reasonably be expected to result.

Note: If a test article (investigational new drug, device, or biologic) is involved, name the test article and state whether the 30-day interval between submission of offeror's certification to the Food and Drug Administration (FDA) and its response has elapsed or has been waived and/or whether the FDA has withheld or restricted use of the test article.

Collaborating Site(s)

When research involving human subjects will take place at collaborating site(s) or other performance site(s), the offeror must provide in this section of its proposal a list of the collaborating sites and their assurance numbers. Further, if you are awarded a contract, you must obtain in writing, and keep on file, an assurance from each site that the previous points have been adequately addressed at a level of attention that is at least as high as that documented at your organization. Site(s) added after an award is made must also adhere to the above requirements.

(11) Required Education in the Protection of Human Research Participants

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for contracts for research involving human subjects. This policy announcement is found in the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>. Offerors should review the policy announcement prior to submission of their offers. The following is a summary of the Policy Announcement:

For any solicitation for research involving human subjects, the offeror shall provide in its technical proposal the following information: (1) a list of the names of the principal investigator and any other individuals proposed under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program completed (or to be completed prior to the award of the contract) for each named personnel; (3) a one sentence description of the program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Curricula that are readily available and meet the educational requirement include the NIH on-line tutorial, titled "Protection of Human Research Subjects: Computer-Based Training for Researchers," available at <http://ohsr.od.nih.gov/cbt/>. You may download the information at this site at no cost and modify it, if desired. In addition, the University of Rochester has made its training program available for individual investigators. Completion of this program will also satisfy the educational requirement. The University of Rochester manual can be obtained through Centerwatch, Inc. at http://www.centerwatch.com/order/pubs_profs_protect.html. If an institution already has developed educational programs on the protection of research participants, completion of these programs also will satisfy the educational requirement.

In addition, prior to the substitution of the principal investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the contractor shall provide the contracting officer with the title of the education program and a one sentence description of the program that the replacement has completed.

(12) Inclusion of Women and Minorities in Research Involving Human Subjects

It is NIH policy that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. The Director, NIH, may determine that exclusion under other circumstances is acceptable, upon the recommendation of an Institute/Center Director, based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43), *and applies to research subjects of all ages*.

All investigators proposing research involving human subjects should read the UPDATED "NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended October 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 at the following web site:

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm

These guidelines contain a definition of **clinical research** adopted in June 2001, as: "(1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive

phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2) Epidemiologic and behavioral studies; and (3) Outcomes research and health services research" (<http://www.nih.gov/news/crp/97report/execsum.htm>).

Information Required for ALL Clinical Research Proposals

This solicitation contains a review criterion addressing the adequacy of: (1) the offeror's plans for inclusion of women and minorities in the research proposed; or (2) the offeror's justification(s) for exclusion of one or both groups from the research proposed.

Provide information on the composition of the proposed study population in terms of sex/gender and racial/ethnic groups and provide a rationale for selection of such subjects in response to the requirements of the solicitation. The description may include (but is not limited to) information on the population characteristics of the disease or condition being studied in the planned research, and/or described in the statement of work, national and local demography, knowledge of the racial/ethnic/cultural characteristics of the population, prior experience and collaborations in recruitment and retention of the populations and subpopulations to be studied, and the plans, arrangements and letters of commitment from relevant community groups and organizations for the planned research.

The proposal must include the following information:

- A description of the subject selection criteria
- The proposed dates of enrollment (beginning and end)
- A description of the proposed outreach programs for recruiting women and minorities as subjects
- A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group
- The proposed sample composition using the "Targeted/Planned Enrollment Table"(see Section J, Attachments)

NOTE 1: For all proposals, use the ethnic and racial categories and complete the "Targeted/Planned Enrollment Table in accordance with the Office of Management and Budget (OMB) Directive No. 15, which may be found at: <http://www.whitehouse.gov/OMB/fedreg/ombdir15.html>

NOTE 2: If this is an Indefinite Delivery, Indefinite Quantity (IDIQ) or Requirements contract as defined in FAR 16.5, the proposal should describe in general terms how it will comply with each bulleted item above for each task order. When the Government issues a task order request for proposal, each of the bulleted information items must be fully and specifically addressed in the proposal.

Standards for Collecting Data. When you, as a contractor, are planning data collection items on race and ethnicity, you shall use, at a minimum, the categories identified in OMB Directive No. 15. The collection of greater detail is encouraged. However, you should design any additional, more detailed items so that they can be aggregated into these required categories. Self-reporting or self-identification using two separate questions is the preferred method for collecting data on race and ethnicity. When you collect race and ethnicity separately, you must collect ethnicity first. You shall offer respondents the option of selecting one or more racial designations. When you collect data on race and ethnicity separately, you shall also make provisions to report the number of respondents in each racial category who are Hispanic or Latino. When you present aggregate data, you shall provide the number of respondents who selected only one category, for each of the five racial categories. If you collapse data on multiple responses, you shall make available, at a minimum, the total number of respondents reporting "more than one race." Federal agencies shall not present data on detailed categories if doing so would compromise data quality or confidentiality standards.

In addition to the above requirements, solicitations for **NIH defined Phase III clinical trials**¹ require that: a) all proposals and/or protocols provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide:

¹See NIH Guide http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm for the Definition of an "NIH-Defined Phase III clinical trial."

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm,
Definitions - Significant Difference),

by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable; and b) all contractors to report annually cumulative subject accrual, and progress in conducting analyses for sex/gender and race/ethnicity differences.

Offerors may obtain copies of the Updated Guidelines from the sources above or from the contact person listed in the solicitation.

Also, the proposal must include one of the following plans:

- Plans to conduct valid analysis to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups, OR
- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups, OR
- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

Use the form in Section J, Attachments, entitled, "Targeted/Planned Enrollment Table," when preparing your response to the solicitation requirements for inclusion of women and minorities.

Unless otherwise specified in this solicitation, the Government has determined that the work required by this solicitation does not involve a sex/gender specific study or a single or limited number of minority population groups. Therefore, the NIH believes that the inclusion of women and minority populations is appropriate for this project. (See Section M of this RFP for more information about evaluation factors for award.)

Use the format for the Annual Technical Progress Report for Clinical Research Study Populations (See Section J - List of Documents, Exhibits and Other Attachments of the RFP) entitled, "Inclusion Enrollment Report," for reporting in the resultant contract.

(13) Inclusion of Children in Research Involving Human Subjects

It is NIH policy that children (defined below) must be included in all human subjects research, including, but not limited to, clinical trials, conducted under a contract funded by the NIH, unless there are *clear and compelling* reasons not to include them. **(See examples of Justifications for Exclusion of Children below).** For the purposes of this policy, contracts involving human subjects include categories that would otherwise be exempt from the DHHS Policy for Protection of Human Research Subjects (sections 101(b) and 401(b) of 45 CFR 46), such as surveys, evaluation of educational interventions, and studies of existing data or specimens that should include children as participants. This policy applies to both domestic and foreign research contracts.

For purposes of this policy, a child is defined as an individual under the age of 21 years.

All offerors proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" which was published in the NIH Guide for Grants and Contracts on March 6, 1998 and is available at the following URL address:

<http://www.nih.gov/grants/guide/notice-files/not98-024.html>

Offerors also may obtain copies from the contact person listed in the RFP.

Inclusion of children as participants in research must be in compliance with all applicable subparts of 45 CFR 46 as well as other pertinent laws and regulations whether or not such research is otherwise exempted from 45 CFR 46. Therefore, any proposals must include a description of plans for including children, unless the offeror presents clear and convincing justification for an exclusion. The "Human Subjects" section of your technical proposal should

provide either a description of the plans to include children and a rationale for selecting or excluding a specific age range of child, or an explanation of the reason(s) for excluding children as participants in the research. This solicitation contains a review criterion addressing the adequacy of: (1) the plans for including children as appropriate for the scientific goals of the research; and/or (2) the justification of exclusion of children or exclusion of a specific age range of children.

When children are included, the plan also must include a description of: (1) the expertise of the investigative team for dealing with children at the ages included; (2) the appropriateness of the available facilities to accommodate the children; and, (3) the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation.

Justifications for Exclusion of Children

It is expected that children will be included in all research involving human subjects unless one or more of the following exclusionary circumstances can be fully justified:

- The objective of the solicitation is not relevant to children.
 - There are laws or regulations barring the inclusion of children in the research to be conducted under the solicitation.
 - The knowledge being sought in the research is already available for children or will be obtained from another ongoing study, and an additional study will be redundant. You should provide documentation of other studies justifying the exclusion.
 - A separate, age-specific study in children is warranted and preferable. Examples include:
- The relative rarity of the condition in children, as compared with adults (in that extraordinary effort would be needed to include children); or
- The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network; or
- Issues of study design preclude direct applicability of hypotheses and/or interventions to both adults and children (including different cognitive, developmental, or disease stages of different age-related metabolic processes); or
- Insufficient data are available in adults to judge potential risk in children (in which case one of the research objectives could be to obtain sufficient adult data to make this judgment). While children usually should not be the initial group to be involved in research studies, in some instances, the nature and seriousness of the illness may warrant their participation earlier based on careful risk and benefit analysis; or
- Study designs aimed at collecting additional data on pre-enrolled adult study subjects (e.g., longitudinal follow-up studies that did not include data on children);
- Other special cases justified by the offeror and found acceptable to the review group and the Institute Director

Definition of a Child

For the purpose of this solicitation, a child is defined as an individual under the age of 21 years.

The definition of child described above will pertain to this solicitation (notwithstanding the FDA definition of a child as an individual from infancy to 16 years of age, and varying definitions employed by some states). Generally, State laws define what constitutes a “child,” and such definitions dictate whether or not a person can legally consent to participate in a research study. However, State laws vary, and many do not address when a child can consent to participate in research. Federal Regulations (45 CFR 46, subpart D, Sec.401-409) address DHHS protections for children who participate in research, and rely on State definitions of “child” for consent purposes. Consequently, the children included in this policy (persons under the age of 21) may differ in the age at which their own consent is required and sufficient to participate in research under State law. For example, some states consider a person age 18 to be an adult and therefore one who can provide consent without parental permission.

(14) Privacy Act (Treatment of Proposal Information)

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The NIH is requesting the information called for in this RFP pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.

Failure to provide any or all of the requested information may result in a less than adequate review.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of NIH contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

The information provided by you may be routinely disclosed for the following purposes:

- to the cognizant audit agency and the General Accounting Office for auditing.
- to the Department of Justice as required for litigation.
- to respond to congressional inquiries.
- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

(15) Selection of Offerors

- a) The acceptability of the scientific and technical portion of each research contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.
- b) The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.
- c) If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.
- d) If the Government intends to conduct discussions prior to awarding a contract-
 - (1) Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal, but may be considered in rating proposals for the purpose of establishing the competitive range.

- (2) The Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or written discussions will be conducted with all offerors in the competitive range.

While it is this Institute's policy to conduct discussions with all offerors in the competitive range, the Institute reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected sources in accordance with HHSAR 315.370.

- e) The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.
- f) The Institute reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet the Institute's requirements. Synopses of awards exceeding \$25,000 will be published in the Commerce Business Daily and FedBizOpps.

(16) Small Business Subcontracting Plan

If the proposed contract exceeds a total estimated cost of \$500,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation, Attachment _ to this RFP is an example of such a plan.

- a) THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.
- b) *The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.*
- c) *The offeror understands that:*
 - (1) No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.
- (1) An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HubZone Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.
 - (2) If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.
 - (3) Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.

- (4) It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HubZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other.
 - (5) The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.
- d) Each plan must contain the following:
- (1) Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.
 - (1) A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.
 - (2) A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned and/or Service Disabled Veteran-Owned Small Business Concerns.
 - (3) A description of the method used to develop the subcontracting goals.
 - (4) A description of the method used to identify potential sources for solicitation purposes.
 - (5) A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.
 - (6) The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.
 - (7) A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.
 - (8) Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of \$500,000 adopt a plan similar to the plan agreed upon by the offeror.
 - (9) Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (SF 294 and SF 295) to the Government.
 - (10) List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

For additional information about each of the above elements required to be contained the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan, and the Sample Subcontracting Plan which is provided as an attachment to this RFP in SECTION J.

(17) HUBZone Small Business Concerns

Small Business offerors located in underutilized business zones, called "HUBZones," will be evaluated in accordance with FAR Clause 52.219-4, NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS, which is incorporated by reference in ARTICLE I.3. of this solicitation. Qualified HUBZone firms are identified in the Small Business Administration website at <http://www.sba.gov/hubzone>.

(18) Extent of Small Disadvantaged Business Participation

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Industry Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed \$500,000 (\$1,000,000 for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b)). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

The factor entitled "Extent of Small Disadvantaged Business Participation" as set forth under the Evaluation Criteria in Section M shall be used for evaluation purposes. Credit under this evaluation factor is not available to SDB concerns that receive a Price Evaluation Adjustment (PEA) under FAR 19.11. Therefore, an SDB will be evaluated on this factor only if that SDB concern waives the PEA. **Waiver of the price evaluation adjustment shall be clearly stated in the proposal.**

The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) codes, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). The NAICS codes can be found at: <http://www.sba.gov/size>

The Department of Commerce website for the annual determination is:

<http://www.arnet.gov/References/sdbadjustments.htm>

Offerors shall include with their offers, SDB targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized NAICS Industry Subsector(s). The applicable authorized NAICS Industry Subsector(s) for this project is (are) identified elsewhere in this RFP. A total target for SDB participation by the prime contractor, that includes any joint ventures and team members, shall be provided as well as a total target for SDB participation by subcontractors. In addition, offerors must provide information that describes their plans for meeting the targets set forth in their proposal. **This information shall be provided in one clearly marked section of the Business Proposal, which shall describe the extent of participation of SDB concerns in the performance of the contract.**

If the evaluation factor in this solicitation includes an SDB evaluation factor or subfactor that considers the extent to which SDB concerns are specifically identified, the SDB concerns considered in the evaluation shall be listed in any resultant contract. Offerors should note that addressing the extent of small disadvantaged business participation is **not in any way intended to be a substitute** for submission of the subcontracting plan, if it is required by this solicitation. An example of the type of information that might be given (in addition to the narrative describing the plan for meeting the targets) follows:

EXAMPLE

Targets for SDB Participation - NAICS Industry Subsector 223

	SDB Percentage of Total Contract Value	SDB Dollars
Total Contract Value- \$1,000,000	25%	\$250,000
SDB Participation by Prime	10%	\$100,000
(Includes joint venture partners and team arrangements)*		
SDB Participation by subcontractors	15%	\$150,000

***NOTE:** FAR Subpart 9.6 defines "Contractor team arrangements" to include two or more companies forming a partnership or joint venture to act as a potential prime contractor, or a potential prime contractor who agrees with one or more companies to have them act as its subcontractors on a specific contract or acquisition program. For purposes of evaluation of the SDB participation factor, FAR 19.1202-4 requires that SDB joint ventures and teaming arrangements at the prime level be presented separately from SDB participation by subcontractors.

(19) Reimbursement of Costs for Independent Research and Development Projects (Commercial Organizations Only)

The primary purpose of the Public Health Service (PHS) is to support and advance independent research within the scientific community. This support is provided in the form of contracts and grants totaling approximately 7 billion dollars annually. PHS has established effective, time tested and well recognized and accepted procedures for stimulating and supporting this independent research by selecting from multitudes of proposals those research projects most worthy of support within the constraints of its appropriations. The reimbursement of independent research and development costs not incidental to product improvement, through the indirect cost mechanism, would circumvent this competitive process.

To ensure that all research and development projects receive similar and equal consideration, all offerors may compete for direct funding for independent research and development projects they consider worthy of support by submitting those projects to the appropriate Public Health Service grant and/or contract office for review. Since these projects may be submitted for direct funding, the successful offeror agrees that no costs for any independent research and development project, including applicable indirect costs, will be claimed under any contract resulting from this solicitation.

(20) Salary Rate Limitation in Fiscal Year 2002 **

Offerors are advised that pursuant to P.L. 107-116, no NIH Fiscal Year 2002 (October 1, 2001 - September 30, 2002) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I*. The salary rate limitation set by P.L. 107-116 applies only to Fiscal Year 2002 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I* annual salary rate limit also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. 107-116 states in pertinent part:

"None of the funds appropriated in this Act for the National Institutes of Health, the Agency for Healthcare Research and Quality, and the Substance Abuse, and Mental Health Services Administration shall be used to pay the salary of an individual through a grant or extramural mechanism at a rate in excess of Executive Level I."

Information regarding the FY-2002 rate can be found at: <http://www.opm.gov/oca/02tables/ex.pdf>

(21) Institutional Responsibility Regarding Conflicting Interests of Investigators

EACH INSTITUTION MUST:

- (a) Maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR Part 50 Subpart F and/or 45 CFR Part 94 as appropriate and inform each investigator of the Institution's policy, the Investigator's reporting responsibilities, and the applicable regulations. If the Institution carries out the NIH funded research through subgrantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.
- (b) Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.
- (c) Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research for which the NIH funding is sought; and (ii) in entities whose financial interests would reasonably appear to be affected by the research. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.
- (d) Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.
- (e) Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and (2) in the case of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.
- (f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.
- (g) Certify, in each application/proposal for funding to which the regulations applies, that:
 - 1) there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH;
 - 2) prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accord with the regulations; and for any interest that the Institution identifies as conflicting subsequent to the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification;
 - 3) the Institution agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and
 - 4) the Institution will otherwise comply with the regulations.

INSTITUTIONAL MANAGEMENT OF CONFLICTING INTERESTS

- (a) The designated official(s) must: (1) review all financial disclosures; and (2) determine whether conflict of interest exists, and if so, determine what actions should be taken by the Institution to manage, reduce or eliminate such conflict of interest. **A conflict of interest exists when the designated official(s) reasonably**

determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research.

Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests include, but are not limited to:

- (i) public disclosure of significant financial interests;
 - (ii) monitoring of research by independent reviewers;
 - (iii) modification of the research plan;
 - (iv) disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;
 - (v) divestiture of significant financial interests; or
 - (vi) severance of relationships that create actual or potential conflicts of interests.
- (b) An Institution may require the management of other conflicting financial interests in addition to those described in paragraph (a) of this section, as the Institution deems appropriate.

(22) ROTC Access and Federal Military Recruiting on Campus

Section 514 of the FY 1997 Appropriations Act prohibits NIH from providing contract funds to educational institutions that the Secretary of Defense determines have a policy or practice (regardless of when implemented) that either prohibits, or in effect prevents (1) the maintaining, establishing, or operation of a unit of the Senior Reserve Officer Training Corps at the covered education entity; or (2) a student at the covered educational entity from enrolling in a unit of the Senior Reserve Officer Training Corps at another institution of higher education.

Further, contract funds may not be provided to educational institutions that have a policy or practice that prohibits or prevents (1) entry to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of Federal military recruiting; or (2) access by military recruiters for purposes of Federal military recruiting to information pertaining to students (who are 17 years of age or older) enrolled at the covered educational entity.

(23) Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 1998)

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: <http://www.arnet.gov/far/>.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

- a) Submission of Offers in the English Language, FAR Clause 52.214-34, (April 1991).
- b) Submission of Offers in U.S. Currency, FAR Clause 52.214-35, (April 1991).
- c) Facsimile Proposals, FAR Clause 52.215-5, (October 1997).
- d) Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997).
- e) Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).
- f) Preaward On-Site Equal Opportunity Compliance Evaluation, (Over \$10,000,000), FAR Clause 52.222-24, (February 1999).

TECHNICAL PROPOSAL INSTRUCTIONS

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

(1) Technical Discussions

The technical discussion included in the technical proposal should respond to the items set forth below:

a) Statement of Work

(1) Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.

(2) Approach

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

(3) Methods

Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

(4) Schedule

Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

b) Personnel

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

(1) Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

(2) Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

(3) Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

- The specific items or expertise they will provide.
- Their availability to the project and the amount of time anticipated.
- Willingness to act as a consultant.
- How rights to publications and patents will be handled.

(4) Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

(2) Technical Evaluation

Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in the Technical Evaluation Criteria (SEE SECTION M).

(3) Additional Technical Proposal Information

- a) Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.
- b) The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

(4) Other Considerations

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

- a) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.
- b) Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.

- c) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.
- d) Other factors you feel are important and support your proposed research.
- e) Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

(5) Information Technology Systems Security

If this project involves Information Technology, the proposal must present a detailed outline of its proposed Information Technology systems security program which complies with the requirements of the Statement of Work, the Computer Security Act of 1987 Office of Management and Budget (OMB) Circular A-130, Appendix III, "Security of Federal Automated Information Systems," and the DHHS Automated Information Systems Security Program Handbook (Release 2.0, dated May, 1994). The proposal will also need to include similar information for any subcontract proposed.

NOTE: OMB A-130 is accessible via web site: <http://www.whitehouse.gov/WH/EOP/OMB/html/circular.html>

BUSINESS PROPOSAL INSTRUCTIONS

(1) Basic Cost/Price Information

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

(2) Cost and Pricing Data

1. General Instructions

A. You must provide the following information on the first page of your pricing proposal:

- (1) Solicitation, contract, and/or modification number;
- (2) Name and address of offeror;
- (3) Name and telephone number of point of contact;
- (4) Name of contract administration office (if available);
- (5) Type of contract action (that is, new contract, change order, price revision/redetermination, letter contract, unpriced order, or other);
- (6) Proposed cost; profit or fee; and total;
- (7) Whether you will require the use of Government property in the performance of the contract, and, if so, what property;
- (8) Whether your organization is subject to cost accounting standards; whether your organization has submitted a CASB Disclosure Statement, and if it has been determined adequate; whether you have been notified that you are or may be in noncompliance with your Disclosure Statement or CAS, and, if yes, an explanation; whether any aspect of this proposal is inconsistent with your disclosed practices or applicable CAS, and, if so, an explanation; and whether the proposal is consistent with your established estimating and accounting principles and procedures and FAR Part 31, Cost Principles, and, if not, an explanation;
- (9) The following statement: This proposal reflects our estimates and/or actual costs as of this date and conforms with the instructions in FAR 15.403-5(b)(1) and Table 15-2. By submitting this proposal, we grant the Contracting Officer and authorized representative(s) the right to examine, at any time before award, those records, which include books, documents, accounting procedures and practices, and other data, regardless of type and form or whether such supporting information is specifically referenced or included in the proposal as the basis for pricing, that will permit an adequate evaluation of the proposed price;
- (10) Date of submission; and
- (11) Name, title and signature of authorized representative.

B. In submitting your proposal, you must include an index, appropriately referenced, of all the cost or pricing data and information accompanying or identified in the proposal. In addition, you must annotate any future additions and/or revisions, up to the date of agreement on price, or an earlier date agreed upon by the parties, on a supplemental index.

C. As part of the specific information required, you must submit, with your proposal, cost or pricing data (that is, data that are verifiable and factual and otherwise as defined at FAR 15.401). You must clearly identify on your cover sheet that cost or pricing data are included as part of the proposal. In addition, you must submit with your proposal any information reasonably required to explain your estimating process, including--

- (1) The judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data; and
- (2) The nature and amount of any contingencies included in the proposed price.

D. You must show the relationship between contract line item prices and the total contract price. You must attach cost-element breakdowns for each proposed line item, using the appropriate format prescribed in the

"Formats for Submission of Line Item Summaries" section of this table. You must furnish supporting breakdowns for each cost element, consistent with your cost accounting system.

- E. When more than one contract line item is proposed, you must also provide summary total amounts covering all line items for each element of cost.
- F. Whenever you have incurred costs for work performed before submission of a proposal, you must identify those costs in your cost/price proposal.
- G. If you have reached an agreement with Government representatives on use of forward pricing rates/factors, identify the agreement, include a copy, and describe its nature.
- H. As soon as practicable after final agreement on price or an earlier date agreed to by the parties, but before the award resulting from the proposal, you must, under the conditions stated in FAR 15.406-2, submit a Certificate of Current Cost or Pricing Data.

2. Cost Elements

Depending on your system, you must provide breakdowns for the following basic cost elements, as applicable:

- A. **Materials and services.** Provide a consolidated priced summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.). Include raw materials, parts, components, assemblies, and services to be produced or performed by others. For all items proposed, identify the item and show the source, quantity, and price. Conduct price analyses of all subcontractor proposals. Conduct cost analyses for all subcontracts when cost or pricing data are submitted by the subcontractor. Include these analyses as part of your own cost or pricing data submissions for subcontracts expected to exceed the appropriate threshold in FAR 15.403-4. Submit the subcontractor cost or pricing data as part of your own cost or pricing data as required in paragraph 2.A.(2) of this table. These requirements also apply to all subcontractors if required to submit cost or pricing data.
 - (1) *Adequate Price Competition.* Provide data showing the degree of competition and the basis for establishing the source and reasonableness of price for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding, or expected to exceed, the appropriate threshold set forth at FAR 15.403-4 priced on the basis of adequate price competition. For interorganizational transfers priced at other than the cost of comparable competitive commercial work of the division, subsidiary, or affiliate of the contractor, explain the pricing method (see FAR 31.205-26(e)).
 - (2) *All Other.* Obtain cost or pricing data from prospective sources for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding the threshold set forth in FAR 15.403-4 and not otherwise exempt, in accordance with FAR 15.403-1(b) (i.e., adequate price competition, commercial items, prices set by law or regulation or waiver). Also provide data showing the basis for establishing source and reasonableness of price. In addition, provide a summary of your cost analysis and a copy of cost or pricing data submitted by the prospective source in support of each subcontract, or purchase order that is the lower of either \$10,000,000 or more, or both more than the pertinent cost or pricing data threshold and more than 10 percent of the prime contractor's proposed price. The Contracting Officer may require you to submit cost or pricing data in support of proposals in lower amounts. Subcontractor cost or pricing data must be accurate, complete and current as of the date of final price agreement, or an earlier date agreed upon by the parties, given on the prime contractor's Certificate of Current Cost or Pricing Data. The prime contractor is responsible for updating a prospective subcontractor's data. For standard commercial items fabricated by the offeror that are generally stocked in inventory, provide a separate cost breakdown, if priced based on cost. For interorganizational transfers priced at cost, provide a separate breakdown of cost elements. Analyze the cost or pricing data and submit the results of your analysis of the prospective source's proposal. When submission of a prospective source's cost or pricing data is required as described in this paragraph, it must be included along with your own cost or pricing data submission, as part of your own cost or pricing data. You must also submit any other cost or pricing data obtained from a subcontractor, either actually or by specific identification, along with the results of any analysis performed on that data.

- B. **Direct Labor.** Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category, and furnish bases for estimates.
- C. **Indirect Costs.** Indicate how you have computed and applied your indirect costs, including cost breakdowns. Show trends and budgetary data to provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation.
- D. **Other Costs.** List all other costs not otherwise included in the categories described above (e.g., special tooling, travel, computer and consultant services, preservation, packaging and packing, spoilage and rework, and Federal excise tax on finished articles) and provide bases for pricing.
- E. **Royalties.** If royalties exceed \$1,500, you must provide the following information on a separate page for each separate royalty or license fee:
- (1) Name and address of licensor.
 - (2) Date of license agreement.
 - (3) Patent numbers.
 - (4) Patent application serial numbers, or other basis on which the royalty is payable.
 - (5) Brief description (including any part or model numbers of each contract item or component on which the royalty is payable).
 - (6) Percentage or dollar rate of royalty per unit.
 - (7) Unit price of contract item.
 - (8) Number of units.
 - (9) Total dollar amount of royalties.
 - (10) If specifically requested by the Contracting Officer, a copy of the current license agreement and identification of applicable claims of specific patents (see FAR 27.204 and 31.205-37).
- F. **Facilities Capital Cost of Money.** When you elect to claim facilities capital cost of money as an allowable cost, you must submit Form CASB-CMF and show the calculation of the proposed amount (see FAR 31.205-10).

3. **Formats for Submission of Line Item Summaries**

The detailed breakdown shall be in the format as shown on the form **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours** (SECTION J, List of Attachments). For each separate cost estimate, the offeror must furnish a breakdown by cost element as indicated above. In addition, summary total amounts shall be furnished. In the event the RFP cites specific line items, by number, a cost breakdown for each line item must be furnished.

To assist in the preparation of future cost estimates, the Projected Consumer Price Index may be accessed at: <http://amb.nci.nih.gov/cpi.htm>

4. There is a clear distinction between submitting cost or pricing data and merely making available books, records, and other documents without identification. The requirement for submission of cost or pricing data is met when all accurate cost or pricing data reasonably available to the offeror have been submitted, either actually or by specific identification, to the Contracting Officer or an authorized representative. As later information comes into your possession, it should be submitted promptly to the Contracting Officer in a manner that clearly shows how the information relates to the offeror's price proposal. The requirement for submission of cost or pricing data continues up to the time of agreement on price, or an earlier date agreed upon between the parties if applicable.
5. By submitting your proposal, you grant the Contracting Officer or an authorized representative the right to examine records that formed the basis for the pricing proposal. That examination can take place at any time before award. It may include those books, records, documents, and other types of factual information (regardless of form or whether the information is specifically referenced or included in the proposal as the basis for pricing) that will permit an adequate evaluation of the proposed price.

(3) Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data [FAR Clause 52.215-20 (October 1997)]

(a) Exceptions from cost or pricing data.

- (1) In lieu of submitting cost or pricing data, offerors may submit a written request for exception by submitting the information described in the following subparagraphs. The Contracting Officer may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted, and whether the price is fair and reasonable.
 - (i) Identification of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.
 - (ii) Commercial item exception. For a commercial item exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include--
 - (A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;
 - (B) For market-priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;
 - (C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.
- (2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.

(b) Requirements for cost or pricing data. If the offeror is not granted an exception from the requirement to submit cost or pricing data, the following applies:

- (1) The offeror shall prepare and submit cost or pricing data and supporting attachments in accordance with Table 15-2 of FAR 15.408.
- (2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2.

Alternate I (October 1997). As prescribed in 15.408(l), substitute the following paragraph (b)(1) for paragraph (b)(1) of the basic provision:

(b) (1) The offeror shall submit cost or pricing data and supporting attachments in the following format:

The format specified in paragraph L.2.c.(4) Cost and Pricing Data, subparagraph 3. Formats for Submission of Line Item Summaries shall be used for the submission cost information. Submission of all other cost or pricing data shall be in accordance with Table 15-2 in FAR 15.408.

(4) Total Compensation Plan - Instructions

- a) Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. All offerors AS A PART OF THEIR BUSINESS PROPOSAL WILL SUBMIT a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.
- b) The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).
- c) Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

(5) Total Compensation Plan - Evaluation

a) **Total Compensation Plan (Professional Employees)**

In establishing compensation levels for professional employees, the total compensation (both salaries and fringe benefits) proposed shall reflect a clear understanding of the requirements of the work to be accomplished and the suitability of the proposed compensation structure to obtain and retain qualified personnel to meet mission objectives. The salary rates or ranges must recognize the distinct differences in professional skills and the complexity of varied disciplines as well as job difficulty. Proposals offering total compensation levels less than currently being paid by the predecessor Contractor for the same work will be evaluated, in addition to the above, on the basis of maintaining program continuity, uninterrupted work of high quality, and availability of required competent professional employees. Offerors are cautioned that instances of lowered compensation for essentially the same professional work may be considered a lack of sound management judgment in addition to indicating a lack of understanding of the requirement.

b) **Cost (Professional Compensation)**

Proposals which are unrealistically low or do not reflect a reasonable relationship of compensation to the professional job categories so as to impair the Contractor's ability to recruit and retain competent professional employees, may be viewed as reflecting a failure to comprehend the complexity of the contract requirements. The Government is concerned with the quality and stability of the work force to be employed on this contract. The compensation data required will be used in evaluation of the offeror's understanding of the contract requirements.

c) **Other (Labor Relations)**

An assessment of the potential for adverse effect upon performance and maintenance of the required number of professional employees with requisite skills resulting from an unrealistically low compensation structure will also be made.

d) **Federal Acquisition Regulation Clauses incorporated by Reference**

FAR Clause 52.222-46, Evaluation of Compensation for Professional Employees (FEBRUARY 1993).

(6) Qualifications of the Offeror

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

a) **General Experience**

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

b) **Organizational Experience Related to the RFP**

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

c) **Performance History**

Performance history is defined as meeting contract objectives within **delivery** and **cost schedules** on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

d) **Pertinent Contracts**

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

e) **Pertinent Grants**

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

(7) **Other Administrative Data**

a) **Property**

(1) It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the Contracting Officer. If the offeror is proposing that the Government provide any equipment, other than that specified under Government Furnished Property in the RFP, the proposal must include comprehensive justification which includes:

(a) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.

(b) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.

(2) The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.

- (3) The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractors Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

b) Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38 (MAY 1999)

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232-34, Payment by Electronic Funds Transfer--Other than Central Contractor Registration.

- (1) The solicitation number (or other procurement identification number).
- (2) The offeror's name and remittance address, as stated in the offer.
- (3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
- (4) The name, address, and 9-digit Routing Transit Number of the offeror's financial agent.
- (5) The offeror's account number and the type of account (checking, savings, or lockbox).
- (6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
- (7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9-digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on-line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

c) Financial Capacity

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

d) Incremental Funding

An incrementally funded cost-reimbursement contract is a contract in which the total work effort is to be performed over a multiple year period and funds are allotted, as they become available, to cover discernible phases or increments of performance. The incremental funding technique allows for contracts to be awarded for periods in excess of one year even though the total estimated amount of funds expected to be obligated for the contract are not available at the time of the contract award. If this requirement is specified elsewhere in this RFP, the offeror shall submit a cost proposal for each year. In addition, the following provisions are applicable:

HHSAR 352.232-75, Incremental Funding (January 2001)

(a) It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. Additional funds are intended to be allotted to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.

- (b) The Limitation of Funds clause to be included in the resultant contract shall supersede the Limitation of Cost clause found in the General Provisions.

e) Facilities Capital Cost of Money, FAR 52.215-16, (October 1997)

(This is applicable if you are a commercial organization.)

- (a) Facilities capital cost of money [(see FAR 15.408(h)] will be an allowable cost under the contemplated contract, if the criteria for allowability in subparagraph 31.205-10(a)(2) of the Federal Acquisition Regulation are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.
- (b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

If the offeror elects to claim this cost, the offeror shall specifically identify or propose it in the cost proposal for the contract by checking the appropriate box below.

- ☐ The prospective Contractor has specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).
- ☐ The prospective Contractor has not specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

(8) Subcontractors

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

- a) Willingness to perform as a subcontractor for specific duties (list duties).
- b) What priority the work will be given and how it will relate to other work.
- c) The amount of time and facilities available to this project.
- d) Information on their cognizant field audit offices.
- e) How rights to publications and patents are to be handled.
- f) A complete cost proposal in the same format as the offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:

<http://ocm.od.nih.gov/contracts/rfps/FDP/PDPclausecover.htm>

(9) Proposer's Annual Financial Report

A copy of the organization's most recent annual report must be submitted as part of the business proposal.

(10) Representations and Certifications

One copy of the Representations and Certifications attached as Section K shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of the Representations and Certifications shall be submitted from any proposed subcontractor.

(11) Travel Costs/Travel Policy

a) **Travel Costs - Commercial**

Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

b) **Travel Policy**

One copy of the offeror's (and any proposed subcontractor's) written travel policy shall be included in the business proposal (original only). If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

SECTION M - EVALUATION FACTORS FOR AWARD

1. GENERAL

Selection of an Offeror for contract award will be based on an evaluation of proposals against three factors. The factors in order of importance are: technical, cost/price and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, cost/price and SDB are also important to the overall contract award decision. Technical factors are significantly more important than cost/price or other factors when combined. However, cost/price and SDB participation may become a critical factor in source selection in the event that two or more Offerors are determined to be essentially equal following the evaluation of all technical evaluation factors.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be carefully evaluated. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

2. TECHNICAL EVALUATION CRITERIA

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. Proposals will be judged solely on the written material provided by the Offeror. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

1) Technical Approach/Understanding the Problem **50 points**

Offerors will be evaluated on the basis of a demonstrated understanding of the objectives and needs of the proposed project, and adequacy of approaches proposed in the following areas:

- a) Suitability and rationale of proposed site(s) for specimen selection, acquisition, cataloging, processing and storage. (10 points)
- b) DNA-based typing of HLA class I and II alleles. (10 points)
- c) Measurement of CD8+ and CD4+ T cell responses using state-of-the-art technology and fine mapping of CTL and T helper epitopes. (10 points)
- d) Measurement of neutralizing antibody responses. (5 points)
- e) Generation of viral stocks, amplification of viral genes, HMA analysis and genetic sequencing of fragments. (10 points)
- f) Compilation, analysis and dissemination of data. (5 points)

2) Personnel **30 points**

- a) Principal Investigator: Quality of recent work and relevance to the proposed contract; demonstrated scientific leadership in the areas of: HLA molecular typing; identifying associations between allele(s) group and a particular event or outcome; performance of cellular and humoral assays; CTL and T helper epitope mapping; HIV virus sequencing; compiling and analyzing immunologic and virologic data; and management of samples and data. Adequacy of the Offeror's time availability for the proposed work; documented participation in similar projects; and demonstrated ability to coordinate a team effort at multiple sites if proposed. (10 points)
- b) Scientific and/or technical strength and adequacy of the other professional, technical, and support staff including: the spectrum of expertise offered; qualifications; experience with HLA molecular typing; cellular and humoral immune assays; virus sequencing; and data compilation and analysis. (10 points)
- c) Subcontractors: Documented training, experience and availability of any proposed Subcontractor(s), their documented capability to perform the proposed work, and expertise in similar projects. The logistical adequacy of

the plan for the use of the Subcontractor(s) in the conduct of the project, including the time commitment of the professional and technical staff. Quality of the plan to identify the need to add, replace, or remove the Subcontractor's scientific staff, dependent on the progress or availability of new scientific information. Adequacy of plans for evaluating the performance of Subcontractors.(10 points)

3) Organizational Structure, Facilities, and Resources **20 points**

- a) Adequacy of lines of authority and responsibility for all aspects of the proposed work.
- b) Adequacy of the administrative/logistical approaches including linkage to international sites, and the rationale/procedures for sample/specimen selection, management, receiving, handling, storing, tracking and inventory.
- c) Adequacy of plans to coordinate research between prime and Subcontractor(s)/consultants, and ability to work cohesively as a team in multiple sites, if proposed.
- d) Adequacy and availability of laboratory facilities, equipment and resources necessary to perform assays, particularly at international sites, receive, process, store and ship hazardous and infectious agents, and maintain their activity and viability. (Points A-D = 15 points)
- e) Adequacy of the plan for compliance with all safety guidelines and regulation, including training and monitoring of personnel for exposure to infectious and hazardous reagents
- f) Adequacy of the plan for the orderly transition of data and samples to a successor Contractor or to the Government. (Points E-F = 5 points)

Total 100 points

3. EVALUATION OF TARGETS FOR EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

SDB participation will not be scored, but the Government's conclusion about overall commitment and realism of the Offeror's SDB participation targets will be highly influential in determining the relative merits of the Offeror's proposal and in selecting the Offeror whose proposal is considered to offer the best value to the Government.

The extent of the Offeror's SDB participation targets will be evaluated before determination of the competitive range. The evaluation will be based on information provided by the Offeror in their technical proposal. Evaluation of SDB participation will be a subjective assessment based on consideration of all relevant facts and circumstances. The Government is seeking to determine whether the Offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform as the prime contractor.

Offers will be evaluated on the following sub-factors:

- 1) The extent of an Offeror's commitment to use SDB concerns.
- 2) The complexity and variety of the work SDB concerns are to perform. Greater emphasis will be given for arrangements where the SDB shall be performing work appropriate to the scientific objectives expressed in the statement of work.
- 3) Fairness, reasonableness, and realism of costs proposed by SDB for the work they will perform.

4. HUMAN SUBJECT EVALUATION

If, this research project involves human subjects, NIH Policy requires:

- a) Protection of Human Subjects from Research Risks

The Offeror's proposal must address the involvement of human subjects and protections from research risk relating to their participation, or provide sufficient information on the research subjects to allow a determination by NIAID that a designated exemption is appropriate.

If concerns are identified and you are included in the competitive range, you will be afforded the opportunity to further discuss and/or clarify your position during discussions and in your Final Proposal Revision (FPR). If, after discussions, concerns still exist, your proposal may not be considered further for award.